

January 11, 2011

Dr. Donald Berwick
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4144-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-4144-P
Sections 422.2264 and 423.2264
Translation Requirements for Marketing Materials

Dear Dr. Berwick:

The National Senior Citizens Law Center, a non-profit organization whose principal mission is to protect the rights of low-income older adults, submits these comments with respect to the above referenced Notice of Proposed Rulemaking (NPRM), 75 Fed. Reg. 71190 (Nov. 22, 2010). In making these comments, we are joined by the National Health Law Program and the Center for Medicare Advocacy, Inc. These comments are limited to one proposed pair of regulations addressing the threshold for translation requirements for marketing materials for Medicare Advantage plans (MA plans) and Medicare prescription drug plans (PDPs) (proposed Sections 422.2264 and 423.2264). As proposed, the regulations would require that plans “must provide translated marketing materials in any language that is spoken by more than 10 percent of the general population in a plan benefit package (PBP) service area.”

We believe that the proposed regulations are seriously flawed and strongly urge CMS not to adopt them. Instead we urge the agency to adopt a threshold standard that requires translation when either a numerical or percentage threshold is met.

Importance of the Issue

Translation of plan materials is a health disparities issue. If limited English proficient beneficiaries are not able to get plan materials in a language they understand they will have a difficult time making good decisions about their health care. They may lose access to an important provider, have difficulty obtaining coverage for a needed prescription drug or enroll in a plan that is not cost-effective for them. The result, in each

case, is less care and, likely, a worse health outcome that is directly linked to the fact that the individual does not speak English very well.

Because this is the first time that CMS has sought to establish specific thresholds to trigger translation requirements anywhere in the Medicare program, these regulations and their content could have importance far beyond the limited area of Part C and D marketing materials which they address. They impact CMS initiatives to address health disparities.

CMS should not adopt these regulations. The 10 percent threshold shuts out most LEP beneficiaries in most states from the right to receive documents that they can use and understand. While we appreciate that the genesis of the regulations was an effort to improve the dismal performance by Medicare plans in translations to date, the regulations as written will do more harm than good by locking in insufficient standards. They would be entirely out of step with other HHS regulations, HHS Title VI guidance, DOJ Title VI guidance and the Title VI guidance of other agencies. See www.lep.gov.

As a substitute for the current proposal, we urge CMS to require that plans “must provide translated marketing materials in any language that is spoken by more than 5 percent of the general population in a plan benefit package (PBP) service area or 500 members of the plan at the start of the plan year, whichever is lower.” We ask further that the regulations provide that plans “must provide translated marketing materials in any language in which the plans undertake other marketing activities directed at beneficiaries.”

The Real World Impact of the Proposed Regulations Would Be To Deny Translation Rights to Most Limited English Proficient Medicare Beneficiaries

Applying CMS’s own methodology, the only beneficiaries in PDP plans who would be entitled to written translations under the proposed regulations would be Spanish speakers in ten states/regions: Arizona, California, Colorado, Florida, Illinois, Nevada, New Jersey, New Mexico, New York and Texas.¹ In 40 other states plus the District of Columbia, no PDP members who are speakers of any language other than English would be entitled to translated marketing material. And nowhere in the entire country would PDP members who speak any language other than Spanish be entitled to materials that they could understand. Although it is more difficult to distill the data for Medicare Advantage plans since plan benefit service areas vary, the impact on MA enrollees would be similar.

In its analysis, CMS asserted that the expected benefit of the proposed requirement would be “that all beneficiaries, regardless of language spoken and national origin, will have

¹ We applied the methodology set out in the May 19, 2010 CMS memo “2010 Update for Marketing Material Language Lookup & Translated Materials Monitoring,” using 2008 American Community Survey (ACS) data.

access to all the information they need to make appropriate decisions about their health care to utilize their Medicare benefits most effectively.” NPRM at 71273. The numbers show that the proposed regulations fall completely short of achieving that goal. Instead, the proposed standards would provide plans a justification for failing to fulfill their Title VI obligations to their members.

The Proposed Regulations Are Inconsistent With Title VI of the Civil Rights Act.

As noted in the NPRM at 71235, the proposed regulations are the first time in which CMS has, by regulation, addressed the language access obligations of Medicare Part C and D plans by establishing specific thresholds as guidelines for CMS review. Those obligations arise from Title VI of the Civil Rights Act, which prohibits national origin discrimination.

We support the agency’s interpretation that Medicare plans are required to comply with Title VI and appreciate the attempt to emphasize that obligation in regulation. Codifying standards reflecting Title VI obligations is an important step and must be done with appropriate consideration of Department of Justice and HHS guidance on how to apply the statute. The guidance calls for a four factor analysis in determining language access requirements, including translation requirements, for federal funds recipients.

The four factors are: (1) the number or proportion of LEP persons served or encountered in the eligible service population; (2) the frequency with which LEP individuals come in contact with the recipient’s program, activity or service; (3) the nature and importance of the recipient’s program, activity, or service; and (4) the resources available to the recipient and costs.²

Nothing in the NPRM indicates that CMS undertook an analysis of the four factors in crafting its proposal; instead, CMS simply carried over subregulatory guidance to which advocates have repeatedly objected.³ In fact, in the regulatory impact analysis portion, the NPRM stated: “We did not consider any other alternatives to our proposed translated marketing requirements.” NPRM at 71274.

As will be shown below, if the four factors are applied to Medicare Advantage plans and to Prescription Drug Plans, it becomes evident that the standards proposed for the regulations are woefully inadequate and are inconsistent with plans’ Title VI obligations.

Factor 1: The number or proportion of LEP persons served or encountered in the

² See HHS Title VI Guidance at 68 Fed. Reg. 47311, 47314 (Aug. 8, 2003); DOJ Guidance at 65 Fed. Reg. 50123 (Aug. 16, 2000)

³ See, e.g., June 8, 2009 NSCLC comments on marketing guidance at www.nsclc.org/areas/medicare-part-d/area_folder.2010-05-17.5076574896/lep-marketing-letter/at_download/attachment .

eligible service population.

In setting a straight 10 percent threshold, CMS has not taken into account numbers of persons served, focusing only on percentages. Close to 30 million beneficiaries are members of Part C or Part D plans. With approximately 19.9% of the general population speaking a “language other than English” at home and 8.6% speaking English “less than ‘very well,’” the number of limited-English speaking (LEP) beneficiaries affected by this regulation is in the millions.⁴

The focus on percentages alone also does not take into account the realities of Part C and D programs. Part D prescription drug plans (PDPs) have service areas that encompass, at a minimum, one state, and in some cases, include several states. Moreover, many plan sponsors offer “national” PDP plans, i.e., plans that offer identical formularies with identical rules and identical co-pay or co-insurance structures. The only variation by region is by premium.⁵ Some of the larger plan sponsors serve millions of beneficiaries. United Health, for example, enrolled 6.5 million beneficiaries in its PDPs in 2010. Many MA plans serve large metropolitan areas. Most Kaiser plans, for example, serve over 20,000 members. One Kaiser MA-PD plan serves 151,000 members.⁶ That single plan could have tens of thousands of members speaking a non-English language. However, under the proposed regulations, Kaiser might not be required to translate any marketing materials for any of them because of the overall demographics of the plan benefit service area. Particularly with large service areas, reliance on percentages alone can deprive very substantial numbers of limited-English proficient (LEP) beneficiaries of access to vital information. It is critical that numerical minimums, not just percentages, be used when setting regulatory thresholds. Otherwise very large numbers of LEP plan members will lose Title VI rights. HHS recognized the need for numerical thresholds in its recently adopted Interim Final Rules governing non-Medicare plans, 75 Fed. Reg.43330, 43337 (July 23, 2010). CMS should do the same.

Factor 2: The frequency with which LEP individuals come in contact with the

⁴ Source: American Community Survey, http://factfinder.census.gov/servlet/STTable?_bm=y&-qr_name=ACS_2009_5YR_G00_S0103&-geo_id=01000US&-ds_name=ACS_2009_5YR_G00_&-lang=en&-format=&-CONTEXT=st

⁵ For the 2011 plan year, one plan sponsor, Humana, is even offering a plan with the same premium nationwide.

⁶ CMS monthly enrollment data for 12/2010, available at www.cms.gov/MCRAdvPartDENrolData/EP/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=2&sortOrder=descending&itemID=CMS1242303&intNumPerPage=10. To function effectively, plans must have significant membership, a fact reinforced by CMS’s recent efforts to actively encourage plan sponsors to eliminate or consolidate duplicative plan offerings and to consider small plan enrollment as a factor militating against approval for program inclusion. See, e.g., DFB Policy Memo 041610 from Danielle Moon (April 16, 2010).

recipient's program, activity or service.

Medicare Advantage plans provide comprehensive health care services to their members. Prescription Drug Plans provide ongoing prescription coverage. LEP plan members thus are in constant contact with their plans and receive a stream of communications during the plan year. An Explanations of Benefits (EOB) for prescription drugs, one of the marketing documents that would be affected by the proposed regulations,⁷ is mailed monthly to plan members. As importantly, beneficiaries receive critical marketing materials annually that define plan benefits and inform members of their rights. These materials are the basis on which beneficiaries make plan choices, choices that lock in most plan members for an entire year. In addition, the marketing communications that are the subject of these regulations are basic tools that members use throughout the year to understand and access their benefits, to determine how to file an appeal, to find in-network providers, to check formulary coverage, etc.

Factor 3: The nature and importance of the program, activity, or service of the recipient of federal financial assistance.

Because MA and PDP plans are providing vital health care services and access to prescription drugs, it is indisputable that the programs are of primary importance to their members. Failure to understand plan benefits impedes access and exacerbates existing health disparities.

Factor 4: The resources available to the recipient and costs.

In setting thresholds, CMS did a partial cost analysis for translations but did not undertake a complete analysis; most importantly, the agency did not weigh these costs against the considerable resources available to plan sponsors.

CMS estimated that the first-year costs of translating 17 required documents⁸ into one language were \$18,325 and noted that translation costs would drop significantly in subsequent years. Because of limited changes to document content, CMS projected that updates in subsequent years would average \$916 per language. NPRM at 71263. The agency also noted that plan benefit sponsors with plans in different service areas could use many of the same documents for multiple plans, further reducing costs.

⁷ See Chapter 3 of the Medicare Marketing Guidelines at 30.7, available at www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage

⁸ The documents to which these regulations would apply are identified in Chapter 3 of the Medicare Marketing Guidelines at 30.7, available at www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage

Although not discussed in the notice, it also would be possible for CMS, because the agency is increasingly relying on standardized model marketing materials, to provide opportunities for pooling of resources by plan sponsors to avoid duplication of costs and even further cut the translation costs for providers.

Even applying CMS's highest projections, the costs to plan sponsors for translations would be minimal. If, for example, a plan with 500 members who spoke Chinese undertook translations of the 17 documents required by CMS into Chinese, the cost per Chinese-speaking member would be only \$3.05/month per member in the initial year. Those per member costs would drop to \$0.15/month per member after the costs of initial translations were absorbed.

When weighed against the size and resources of the affected plan sponsors, these costs are more than reasonable.

A look at the largest Medicare plan sponsor, United Health, is instructive. In 2010, it offered PDPs that together enrolled close to 6.5 million people, while also offering multiple MA products with significant enrollment. Its annual revenues for 2010 are projected to exceed \$90 billion.⁹ Despite these significant resources, under the proposed standard, United Health would not be subject to any translation requirements for its PDP members beyond Spanish in 10 regions. Even if 100,000 or even 500,000 of its members spoke another non-English language, a sponsor like United Health would not be required to spend \$18,000 so that those members could understand the benefits and requirements of their plan, unless that language represented 10 percent of any one service area.

Both the PDP and MA markets are dominated by large players that, like United Health, have significant resources. The ten largest Part D sponsors in 2010 controlled 69 percent of the market.¹⁰ But even "small" local MA-PD plans typically have multi-million dollar budgets.

Not only do plans have substantial resources, they already dedicate large sums to marketing to LEP beneficiaries. The raft of targeted translated mailings of glossy brochures, advertisements in ethnic media, bus ads and billboards that appear every year during the Annual Enrollment Period, not to mention sales events, attest to the marketing dollars directed to the LEP Medicare audience. Significant expenditures are already made to reach LEP beneficiaries but, because CMS does not require it, little to no money is being spent on the core documents that would give these individuals the information they need to make informed choices and understand what is being sold to them. It is also

⁹ Enrollment and revenue figures taken from Standard & Poors Reports.

¹⁰ Source: Kaiser Family Foundation, <http://www.kff.org/medicare/upload/8096.pdf>

worth noting that many of the same health insurers that offer Part C and Part D plans already comply with more stringent translation requirements for their non-Medicare plans governed by state laws. For example, California plans must comply with California Health and Safety Code Section 1367.04 which requires translation of vital documents into threshold languages. The fact that California has the largest managed care market in the nation demonstrates that those translation requirements have not been unduly burdensome on health insurers.

To Effectuate The Purpose of Title VI, CMS Should Adopt Regulations That Require Translations When Either a Numerical or Percentage Threshold Is Met

In light of the four factor analysis, we urge CMS to adopt translation standards for marketing materials that would more effectively respond to the urgent need of diverse beneficiaries for information in a language they can understand and that are consistent with the purposes of Title VI.

We believe that the population percentage, set in the proposal at 10 percent, is too high. However, of even greater concern is the fact that the proposed regulations do not include any numerical threshold as an alternate trigger to the population percentages required for translation obligations. As noted above, the threshold as proposed works disastrously for PDP members, capturing only the Spanish language, and that only in 10 regions. It works no better for MA plan members. Such an outcome is violative of the civil rights of hundreds of thousands of other limited-English proficient beneficiaries.

We propose that CMS both change the current proposed threshold to 5 percent rather than 10 percent and add a numerical floor.

A 5 percent threshold is more responsive to Title VI requirements.

Using 5 percent is consistent with Department of Justice and Health and Human Services Department guidance,¹¹ both of which provide a safe harbor of 1,000 persons or 5 percent of population served or likely to be encountered, whichever is lower. It also would have a significant practical effect, raising the number of PDP regions where Spanish translations would be required from 10 to 20.

In applying this population percentage trigger, we endorse CMS's current methodology of using a very specific data set to monitor compliance. Providing detailed directions such as those found in the HPMS Marketing Material Language Lookup¹² is particularly helpful both for plans to understand their obligations under the regulations and to

¹¹ The DOJ guidance is found at 65 Fed. Reg. 50123 (Aug. 16, 2000); the HHS guidance is at 68 Fed. Reg. 47311, 47319 (Aug. 8, 2003). Both can be accessed at www.lep.gov.

¹² See Note 1.

facilitate enforcement, although we are concerned that the module has not yet been made publicly available, limiting the ability of the public to monitor plan compliance. We also agree that, at the present time, the best data set to use is ACS data for populations 5 years and over. If, over time, better data become available that are specific to Medicare populations, it would then be appropriate for CMS to revisit the question of whether another data set might be more appropriate.

An alternate numerical threshold is absolutely necessary and setting that threshold at 500 plan members is appropriate.

Though changing the percentage threshold to 5 percent is a meaningful improvement, it is still an inadequate step without the inclusion of numerical minimums as well. Even when a 5 percent threshold is used, Spanish-speaking PDP members in 14 regions would still be deprived of rights to translated materials. PDP members who are speakers of other non-English languages would continue to be deprived of any translation rights.

A numerical threshold is necessary to ensure that significant concentrations of LEP beneficiaries living in large, ethnically diverse areas can receive materials. To the extent that the current 10 percent standard in guidance works at all, it imposes obligations primarily on Medicare Advantage plans operating in small PBP service areas with concentrations of particular ethnic minority groups. For example, under the current guidance, despite the fact that nearly 200,000 people in Los Angeles County identify Tagalog as their primary language, plans in Los Angeles County are not required to translate materials into Tagalog since that language represents only two percent of the county's large and ethnically diverse population. Conversely, plans are required to translate materials into German in McIntosh County, North Dakota where 35 percent of the population (1,145 individuals) identify German as their primary language.

In proposing 500 plan members as a numerical minimum, we are guided by the recent DOJ/Department of Treasury/HHS interim final rule governing certain translation obligations for appeals documents for non-Medicare health plans. See 75 Fed. Reg. at 43337. That interim rule uses plan participation at the start of the plan year as the measure. For a plan that covers 100 or more participants at the beginning of a plan year, the threshold is the lesser of 500 participants, or 10 percent of all plan participants.¹³ For a plan that covers fewer than 100 participants at the beginning of a plan year, the threshold is 25 percent of all plan participants being literate only in the same non-English language. We believe it is critically important that language access requirements for Medicare beneficiaries be at least as comprehensive. It would be particularly unfair for individuals to find that upon qualifying for Medicare (based on age or disability), they get significantly less access to translated materials than they had in the non-Medicare market.

¹³ The HHS regulation encompasses individuals "literate only in the same non-English language," a term found in Department of Labor regulations. However, sub regulatory guidance defines that term as covering individuals who do not speak English "very well," the same measure used by CMS.

Therefore, adoption of a 500 plan member trigger for required translation of marketing materials would mirror the numerical portion of the HHS interim final rule and, as shown in the discussion of factor 4, would impose little burden on plans. To determine compliance with this requirement, plans would be required to ask all new members their preferred language and to maintain and compile such data. Current application forms include a question about language preference, but the question is limited to those languages into which a plan already translates documents. It would be a relatively simple matter to modify that question to capture the language preferences of all plan members.

To summarize, we are proposing that CMS adopt a rule that would combine elements of the DOJ and HHS guidance and the HHS Interim Final Rule. Specifically, (drawing from the HHS guidance), we would propose requiring translated marketing materials in any language that either is spoken by more than 5 percent of the general population in a plan benefit package service area or, (drawing from the recent Interim Final Rule), is spoken by more than 500 members of the plan, measured at the beginning of the plan year, whichever is lower.¹⁴

In light of the four factor analysis discussed above, particularly the balance between the critical importance of health plan documents to beneficiaries weighed against the miniscule per member costs to plans, we believe that the combination of the lower thresholds from each standard is reasonable and appropriate.

Plans also should be required to provide translations of required marketing materials in any non-English language in which they conduct marketing activities.

In addition to percentage and numerical thresholds, we also urge CMS to require that any plan sponsor that markets to individuals in languages other than English **must provide the enrollment package documents to prospective members in the language in which the marketing took place**. Thus, for example, if a plan advertises on radio or in magazines in a non-English language or if plan representatives hold marketing events in a non-English language, then the plan must provide all enrollment materials in that language. This requirement should apply whether or not the language meets thresholds. If a plan sponsor makes the business decision to market in a non-English language, it is a simple matter of consumer protection that the sponsor should be required to provide the targeted potential member with all information that CMS considers essential to an informed consumer choice, not just partial information that the plan has decided to translate. The need for these protections is manifest. Advocates report numerous, repeated instances in which limited-English proficient beneficiaries were sold plans in their own language, often with representations that proved untrue, and were then asked to sign English-only documents that they did not understand. It is of critical importance that these individuals get not just slick marketing mailers and high pressure sales pitches, but

¹⁴ If a plan were new to a service area, it would be necessary to make some projections based on membership in other plans offered by the same sponsor or on service area averages. These details could be addressed in guidance.

also vital plan documents that tell them precisely what plan benefit packages include, what their rights are and how to access benefits.¹⁵

Conclusion

We could not urge more strongly that CMS abandon the translation thresholds in proposed Sections 422.2264 and 423.2264, which are inconsistent with the purposes of Title VI. Particularly because this is the first time that CMS has interpreted Title VI by setting specific thresholds, use of this flawed standard would set a very unfortunate agency precedent that, in addition to its significant inconsistencies with Title VI, has a very likely negative effect on the health of LEP beneficiaries. Though CMS may have had the intention of reducing health disparities with the adoption of this regulation, such adoption would in fact have the opposite effect – increasing health access barriers and producing negative outcomes for the very populations it was designed to benefit.

Instead, the agency should adopt the thresholds and protections proposed in these comments which would ensure that many more LEP individuals will get the translations they need without unduly burdening benefit plan sponsors.

Thank you for the opportunity to submit these comments. We would be happy to provide further information. If any questions should arise, please contact Georgia Burke, gburke@nsclc.org.

Sincerely,



Paul Nathanson
Executive Director



Georgia Burke
Co-Directing Attorney, Oakland CA

Doreena Wong, Senior Attorney, National Health Law Program

Brad Plebani, Deputy Director, Center for Medicare Advocacy, Inc.

¹⁵ A similar consumer protection requirement related to voluntary marketing efforts appears in the food labeling regulations of the Food and Drug Administration. FDA requires that all mandatory information on a food label appear in English. If, in addition, a food manufacturer chooses to put information or statements in a non-English language on its labels, the manufacturer must include all FDA required information in that language as well. *See* 21 C.F.R. Sec. 101.15(c)(2) (“If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language.”).