

January 14, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Attention: CMS-4063-FC

To whom it may Concern:

As organizations educating and advocating on health and civil rights issues, and particularly concerned with access to healthcare for individuals who are limited English proficient, we are writing to provide comments to the Interim Final Rule published on December 15, 2003 regarding the Medicare Prescription Drug Discount Card. In particular, we wish to recommend that the Centers for Medicare & Medicaid Services (CMS) include specific requirements that vendors of the drug discount card – the endorsed sponsors – provide language services to ensure that limited English proficient (LEP) Medicare recipients will have meaningful access to the drug discount card. Without providing language services – such as interpreters on a vendor's customer service line or translated materials to explain the enrollment and usage of drug discount cards – many LEP individuals will likely be unable to enroll and receive the benefits from the cards.

According to the 2000 U.S. Census, 4.4 million individuals over the age of 65 speak a language other than English at home. Over 2.3 million of these individuals speak English less than "very well" and would be considered LEP. As most of these individuals are likely eligible for Medicare, it is essential that CMS address their language barriers when implementing the drug discount cards and the Part D prescription drug program as whole. As it is, the level of participation for the general population in the MSP programs is already low despite significant outreach efforts. The opportunity to participate for LEP individuals is further compounded by language barriers, which often add another insurmountable hurdle to enrollment. Particularly for the low-income LEP Medicare beneficiaries – who can receive up to \$600.00 per year in assistance to pay for their prescription drugs – the drug discount cards represent an essential government benefit for which CMS must ensure meaningful access for LEP Medicare

beneficiaries.

The Bush administration has made a number of critical pronouncements about the need for health care providers to ensure meaningful access for people with limited English proficiency. On a number of occasions, the administration has reaffirmed its commitment to Executive Order [EO] 13166, "Improving Access to Services for Persons with Limited English Proficiency". That Order states "Each federal agency shall prepare a plan to improve access to its federally conducted programs and activities by eligible LEP persons." Thus EO 13166 extended the application of Title VI to federal agencies themselves. As EO 13166 applies to the Medicare program "a federally conducted activity" and particularly in regards to the federal funds which will assist low-income beneficiaries, we believe that CMS must require that endorsed sponsors provide meaningful access to LEP Medicare beneficiaries interested in obtaining a drug discount card. To comply with EO 13166, CMS should implement a plan to improve access to all of its Medicare activities, but should initially "given the pendency of these regulations" develop specific provisions that improve access for LEP Medicare beneficiaries to the Medicare drug discount card.

Even if CMS were to determine that the precise language of EO 13166 does not cover a program like the discount drug cards, CMS certainly has the authority to require it from those seeking to participate in this new Medicare program. HHS, through CMS, OMH, OCR, AHRQ, HRSA and other of its subdivisions, has been a leader in recognizing the need to eliminate racial and ethnic disparities in access to Medicare. This is certainly what President Bush had in mind when he declared his intention to put "a priority on access to health care," and the Administration's commitment to Executive Order (EO 13166) and its implementing guidances both further that commitment and offer beacons of light for individuals currently consigned to the shadows of our health care system due to linguistic barriers. The inclusion of language access provisions in these regulations would constitute a concrete example of the Administration's and HHS' ongoing commitment to the concept of ensuring that all individuals have access to health care regardless of race, ethnicity, or language.

We appreciate that CMS indicated in the Interim Final Rule that it plans to publish information and outreach guidelines to provide further interpretations of its regulations. And we recognize that the issue of outreach to LEP populations might be addressed in such guidelines. To date, however, we have been unable to access any guidelines on the CMS website. Thus, we recommend that CMS amend the regulations themselves "and reiterate in any forthcoming information and outreach guidelines" to specifically address information and outreach to LEP populations.

We believe the most appropriate place to include provisions for language services is section 403.806(g) of the Interim Final Rule which addresses sponsor requirements for eligibility. Since Medicare is a federally conducted activity, and because federal funds are being used to provide the low-income subsidy, CMS must ensure its policies conform to the requirements of EO 13166. The subsidy will likely result in many low-income Medicare beneficiaries enrolling in the drug discount card program who previously would not join a pharmacy benefit plan because of cost. The increased enrollment will increase the profitability of operating the drug discount program. And because of the financial gain the endorsed sponsors will reap from these federal funds, they should accept the responsibility of ensuring meaningful access.

We thus recommend that CMS require endorsed sponsors to develop a language services plan to ensure meaningful access for LEP Medicare beneficiaries. Since neither HHS nor CMS has developed a plan for implementing EO 13166 for its federally conducted programs, we suggest that CMS use the Office for Civil Rights Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons) for federally-funded activities as a guide for the drug discount card regulations. As the OCR guidance states, "recipients are required to take reasonable steps to ensure meaningful access to their programs and activities by LEP persons." OCR outlines four factors to utilize in determining the types of language services which should be provided for LEP Medicare beneficiaries. These four factors are: 1. the number or proportion of LEP persons eligible to be served or likely to be encountered by the endorsed sponsor; 2. the frequency with which LEP individuals come in contact with the endorsed sponsor; 3. the nature and importance of the program, activity, or service provided by the program to people's lives; and 4. the resources available to the endorsed sponsor and costs.

We recommend that CMS require endorsed sponsors to address factors 1, 2, and 4. Given the impact on a person's health and well-being, we believe that CMS should conclude that the OCR guidance's third factor "the nature of the program" is sufficiently important to require language services. Individuals may suffer serious "and potentially life-threatening" consequences from a lack of access to prescription drugs, especially low-income beneficiaries who are unable to afford purchasing prescription drugs and will benefit significantly from the low-income subsidy.

RECOMMENDATION: Amend § 403.806(c) to read as follows:

An endorsed sponsor must comply with all applicable Federal and State laws, including the Federal anti-kickback statute (section 1128B(b) of the Act) and develop a language services plan that complies with the four factors designated in the federal HHS Office for Civil Rights'

Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons.

Specifically to address translations of written outreach materials, we recommend that CMS adopt the "safe harbor" provisions outlined in the OCR guidance, as adopted for this arena. Including such standards would provide information to endorsed sponsors as to when documents should be translated.

RECOMMENDATION: Add new § 403.806(g)(8)

- (a) An endorsed sponsor must ensure that translated materials are available in the prevalent languages in the endorsed sponsor's service area.
- (1) The endorsed sponsor must provide written translations of vital documents for each eligible LEP language group that constitutes five percent or 1,000, whichever is less, of the population of persons eligible to be served or likely to be affected or encountered. Translation of other documents, if needed can be provided orally; and
- (2) For language groups that do not fall within paragraph (a) above, or constitute fewer than 50 persons in a language group eligible to be served that reaches the five percent trigger in (a), the recipient does not translate vital written materials but provides written notice in the primary language group of the right to receive competent oral interpretation of those written materials, free of cost.

(b) Vital documents include the drug discount card; enrollment forms; eligibility determination notices; informational brochures describing any of the following: drug discount cards, transitional assistance, formularies, co-pays, cost-sharing, or the low-income subsidy; drug treatment instructions; disenrollment information; and notices of enrollee's rights.

RECOMMENDATION: Amend § 403.806(g)(6) "

An endorsed sponsor must maintain a toll-free customer call center that is open during usual business hours and that provides customer telephone service, including to pharmacists, in accordance with standard business practice. The call center must provide interpreters to assist LEP individuals with any questions, including how and where to use the drug discount card, instructions on taking medications, potential side effects, contraindications, and other necessary

information.

RECOMMENDATION: Amend § 4303.806(g) to add new (5)(vi)

An endorsed sponsor shall provide notice of the services that are available to the LEP persons it serves or, to the extent that a service area exists, that reside in its service area and are eligible for services and shall provide to CMS a description of the notice and the process by which it will provide such notice.

We thank you for the opportunity to provide these comments and look forward to working with you to ensure meaningful access for LEP Medicare beneficiaries to the drug discount card and forthcoming Medicare Part D prescription drug benefit. If you have any questions, please contact Mara Youdelman, National Health Law Program, at 202-289-7661.

Sincerely,

Asian Pacific Islander American Health Forum
Families USA
Mexican American Legal Defense and Educational Fund
National Asian Pacific American Legal Consortium
National Council of La Raza
National Health Law Program
National Immigration Law Center
National Senior Citizens Law Center

cc: Alexander Acosta, Assistant Attorney General for Civil Rights Division, Dept. of Justice
Richard Campanelli, Director, Office for Civil Rights, Dept. of Health and Human Services