NATIONAL HEALTH LAW PROGRAM

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

VIA ELECTRONIC DELIVERY

September 28, 2010

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

RE: Comments on OCIIO-9995-IFC, Interim Final Rule Regarding the Pre-Existing Condition Insurance Plan Program

Dear Madam Secretary:

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, people of color, the elderly, women, children, and people with disabilities. We are pleased to submit these comments on the Interim Final Rules for the Pre-Existing Condition Insurance Plan Program (PCIP) under the Patient Protection and Affordable Care Act (PPACA). NHeLP supports these regulations administering the PCIP because it provides health care coverage to those with pre-existing conditions, many of whom were unable to obtain coverage.

In the discussion below, we offer comments to help strengthen the rules. The comments are delivered in the order of the interim final rules.

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 areas of language access and women's/reproductive health, and we have focused much of our comments on those areas.

COMMENTS AND RECCOMENDATIONS

§ 152.15: Enrollment and Disenrollment Process

Section 152.15 provides the process by which individuals can be enrolled and disenrolled in the PCIP program. In recognition that our nation has a diverse population, with many that speak a language other than English, we strongly urge OCIIO to ensure that the enrollment and disenrollment process be completed in a culturally and linguistically appropriate manner.

Language access is one aspect of cultural competence that is essential to quality care for individuals with limited English proficiency (LEP). According to the American Community Survey, over 55 million people speak a language other than English at home. Nearly 5% of all households are deemed

"linguistically isolated," meaning that every member of the household over age 14 speaks English less than very well. Over 25 million (9% of the population) speak English less than "very well," and for health care purposes may be considered to be LEP.

Health care providers from across the country have reported language difficulties and inadequate funding of language services to be major barriers to LEP individuals' access to health care, and a serious threat to the quality of the care they receive.[1] Research documents how the lack of language services creates a barrier to and diminishes the quality of health care for limited English proficient individuals.[2] Language barriers impact access to care: non-English speaking patients are less likely to use primary and preventive care and public health services, are more likely to use emergency rooms, and once at the emergency room, they receive far fewer services than their English speaking counterparts.[3]

There is significant statutory authority mandating the provision of language services. Section 1557 of PPACA forbid discrimination on the grounds of sex, race, national origin, disability or age in health programs or activities receiving federal financial assistance or by programs administered by an Executive Agency or any entity established under Title I 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 party 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)."[4] Because PCIP is "administered by an Executive agency," the anti-discrimination protections in § 1557 therefore should apply to the PCIP's subject to this interim final rule.

In addition, because federal financial assistance will be used to administer and operate PCIP programs, the PCIPs are additionally subject to Title VI of the Civil Rights Act of 1964.[5] HHS has issued an "LEP Guidance"[6] to ensure that language access is provided by federal fund recipients under Title VI,

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1 L. Ku & A. Freilich, Kaiser Comm'n on Medicaid & the Uninsured, *Caring for Immigrants: Health Care Safety Nets in Los Angeles, New York, Miami, and Houston*, ii-iii (2001), *available at* http://aspe.hhs.gov/hsp/immigration/caring01/report.pdf (last visited Sept. 17, 2010); *see also* Inst. of Medicine, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health*, 71–72 (2002), *available at* http://download.nap.edu/cart/deliver.cgi?record_id=10260&type=pdf_chapter (describing recent survey finding 51% of providers believed patients did not adhere to treatment because of culture or language but 56% reported no cultural competency training).

2 *See, e.g.,* G. Flores, et al*., Errors in medical interpretation and their potential clinical consequences in pediatric encounters,* 111 PEDIATRICS 6, 6-14 (2003), *available at* http://pediatrics.aappublications.org/cgi/content/full/111/1/6 (last visited Sept. 17, 2010); T.K. Ghandi, et al., *Drug complications in outpatients*, 15 J. OF GENERAL INTERNAL MEDICINE, 149, 149-154 (2000); Kathryn Pitkin Derose & David Baker, *Limited English Proficiency and Latinos' Use of Physician Services*, 57 MEDICAL CARE RESEARCH AND REVIEW, 76, 76-91 (2000); *see also*, Jacobs, et. al., *Language Barriers in Health Care Settings: An Annotated Bibliography of the Research Literature* (The California Endowment, Los Angeles, Cal.) (2003).

3 *E.g.* J. Bernstein, et al., *Trained Medical Interpreters in the Emergency Department: Effects on Services, Subsequent Charges, and Follow-up,* 4 J. OF IMMIGRANT HEALTH, 171, 171-76 (2002); I.S. Watt, et al., *The health care experience and health behavior of the Chinese: a survey based in Hull*, 15 J. PUBLIC HEALTH MED. 129 (1993); S.A. Fox & J.A. Stein, *The Effect of Physician-Patient Communication on Mammography Utilization by Different Ethnic Groups*, 29 MED. CARE 1065 (1991).

4 Patient Protection & Affordable Care Act, Pub. L. 111-148, 111-152 § 1557 (2010).

5 Civil Rights Act of 1964, 42 U.S.C. §2000d et. seq.

6 *See* 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),

and requires that language services be provided to LEP individuals in conjunction with all federally funded activities and programs. This would include oral communication for all PCIP enrollees and, when certain thresholds are met, written translated materials.[7] Regardless of whether translated materials are provided, PCIP administrators must ensure that LEP individuals understand the nature and scope of the services, any possible appeal process, enrollment/disenrollment processes and any other pertinent information about PCIP and the services provided under the PCIP program.

Recommendation 1: Language Services Should Be Provided to LEP Applicants and Enrollees

Providing a culturally and linguistically appropriate enrollment/disenrollment process requires PCIP administrators to provide outreach materials that, at a minimum, satisfy the LEP Guidance "Safe Harbor" thresholds. This means that materials should be made available in non-English formats including oral communication about outreach and enrollment to all LEP applicants or potential applicants, regardless of whether written materials are available.

We urge OCIIO to add to § 152.15 new subsection (e) as follows:

(e) Language Services.

(1) A PCIP must provide translated written information about enrollment and disenrollment and all vital notices in a culturally and linguistically appropriate manner.

(A) Information must be translated 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; or

(B) If there are fewer than 50 persons in a language group that reaches the five percent trigger in (a), the PCIP does not translate vital written materials but must provide written notice in the primary language of the LEP language group of the right to receive competent oral interpretation of those written materials, free of cost.

(2) A PCIP must provide meaningful access to LEP individuals through competent oral interpreters for all LEP applicants or potential applicants.

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available at http://www.justice.gov/crt/cor/lep/hhsrevisedlepguidance.pdf.

7 The relevant section from the HHS LEP guidance for written translation states: "Safe Harbor. The following actions will be considered strong evidence of compliance with the recipient's written-translation obligations:(a) The HHS recipient provides 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; or (b) If there are fewer than 50 persons in a language group that reaches the five percent trigger in (a), the recipient does not translate vital written materials but provides written notice in the primary language of the LEP language group of the right to receive competent oral interpretation of those written materials, free of cost. These safe harbor provisions apply to the translation of written documents only. They 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. Conversely, oral interpretation of documents may not substitute for translation of vital written documents. For example, oral interpretation of the rules of a half-way house or residential treatment center may not substitute for translation of a short document containing the rules of the half-way house or residential treatment center and the consequences of violating those rules." *Id*.

Recommendation 2: HHS Should Adopt Policies that Streamline the Documentation Process

We are concerned that the regulation allows PCIPs to require the individual to provide documentation to establish an individual's citizenship, nationality or lawful presence rather than require a data match between the PCIP and federal agencies.

There is significant research documenting the challenges faced by many individuals, including many U.S. citizens, in meeting citizenship documentation requirements. Initially imposed by the Deficit Reduction Act (DRA) for Medicaid, citizenship documentation requirements have resulted in eligible individuals being denied enrollment merely because of paperwork requirements. With specific regard to children, it has been estimated that between 1.4 and 2.9 million children do not have ready access to a birth certificate or passport. A recent study in Oregon demonstrated that teens face insurmountable barriers to family planning services when required to produce documents for citizenship verification.[8] Teens who were required to produce documentation of citizenship very often do not return to receive their confidential medical services; simply the requirement of documentation, itself, has been shown to cause a sharp decline in teens seeking access and receiving services for family planning.[9]

As noted by the Center on Budget and Policy Priorities in analyzing the results of citizenship documentation requirements eight months after DRA implementation, an increasing number of states reported marked declines in Medicaid enrollment, particularly among low-income children. The available evidence also strongly suggested that those being adversely affected are primarily U.S. citizens otherwise eligible for Medicaid who are encountering difficulty in promptly securing documents such as birth certificates and who are remaining uninsured for longer periods of time as a result.[10]

Further, all states already have agreements in place with the Social Security Administration for data matching in Medicaid and CHIP. States also have agreements in place with the Department of Homeland Security to verify immigrant status through the SAVE system. Again, states should be able to amend these existing agreements to cover the new PCIP programs and not have to require documentation directly from applicants unless the data matching does not verify an appropriate eligible status.

Given the difficulties many individuals may have in meeting this requirement, and the goal of the PCIP program to cover individuals when other insurance is unattainable, it is essential that HHS adopt policies that streamline the documentation process as much as possible and relieve applicants from the burden of providing documentation. We strongly believe that any option to require applicants to produce documentation be severely time limited and only in effect until PCIPs can get an agreement in place. The alternative of requiring individuals to provide documentation should not be an option that lasts for the entire length of the PCIP program.

We urge OCIIO to amend § 152.15(a)(3)(ii) to read as follows:

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8 L. Angus & J. DeVoe, *Evidence that the Citizenship Mandate Curtailed Participation in Oregon's Medicaid Family Planning Program*, 29 HEALTH AFFAIRS 4, 694-97 (2010).

9 *Id*.

10 D. Cohen Ross, *New Medicaid Citizenship Documentation Requirement is Taking a Toll: States Report Enrollment Is Down and Administrative Costs Are Up,* Ctr. on Budget & Pol'y Priorities, *available at* http://www.cbpp.org/cms/?fa=view&id=1090 (2007) (last visited Sept. 28, 2010).

(3) A PCIP must verify that an individual is a United States citizen or national or lawfully present in the United States by:

(i) ***having in place an agreement with the Commissioner of Social Security or Secretary of Homeland Security as applicable to v***erify~~ing~~ the individual's citizenship, nationality, or lawful presence with the Commissioner of Security or Secretary of Homeland Security as applicable; or

(ii) ***if the PCIP does not have an agreement in place, the following requirements apply:***

(A) ***the PCIP must amend an existing agreement or enter into a new agreement with the Social Security Administration or Department of Homeland Security, as applicable, within six months of being approved as a PCIP. During the initial six months of operation, the PCIP*** ~~By requiring~~ may require the individual to provide documentation which establishes the individual's citizenship, nationality, or lawful presence.

(B) ***after the date the agreement is entered into and in no case longer than six months, the PCIP must verify the individual's citizenship, nationality, or lawful presence with the Commissioner of Security or Secretary of Homeland Security, as applicable, as described in subparagraph (3)(i).***

(C) ***for all individuals denied PCIP eligibility for failing to provide documentation during the period of time when the PCIP does not have an agreement with the Social Security Administration or Department of Homeland Security, the PCIP must submit the individual's information to the Social Security Administration or Department of Homeland Security, as applicable, as soon as an agreement entered into pursuant to subparagraph (A) is effective. If the individual's citizenship, nationality or lawful presence is verified by the Social Security Administration or Department of Homeland Security, the PCIP must automatically enroll the individual retroactively to the date of the original application.***

Recommendation 3: There Should be Explicit Guidance Laying Out the Procedures Related to the Provision of PCIP Benefits During the Citizenship Verification Period

The regulation should explicitly lay out the procedures related to the provision of PCIP benefits during the verification period. We recommend that HHS model these regulations on Medicaid and the Children's Health Insurance Program (CHIP). In those programs, if the state receives a positive response from SSA as to an applicant's documentation, the person has met the citizenship documentation requirement. If and for so long as the state agency does not hear anything from SSA (i.e., it is not notified that the person's name and SSN do not match), the person receives Medicaid/CHIP benefits, if otherwise eligible, and the state will be reimbursed for applicable expenses.[11] If the SSA notifies the state agency that a person's name and SSN do not match, then the agency must make a "reasonable effort to identify and address" the inconsistency by contacting the individual and by following such other procedures as the Secretary or the state have created.[12]

If the state is unable to resolve the inconsistency, it must notify the person of this fact and give the person 90 days from receipt of the notice either to work with the SSA to resolve the problem, or to then submit the documentation of citizenship.[13] If at the end of this 90-day period, the person has neither resolved the problem with the SSA nor provided the documentation required, then the state agency could

11 *See* Children's Health Insurance Program Reauthorization Act, Pub. L. 111-3 § 211(b)(2)(2009).

12 *See* Social Security Act, 42 U.S.C. § 1396a(ee)(1)(B)(i).

13 *See* id.

send the person a termination notice within 30 days. This notice and review procedure should be subject to the same appeal procedures as is any other termination notice.

We believe these same procedures should apply to PCIPs, and that PCIPs that abide by these procedures should be eligible to receive reimbursement for any expenditures made on behalf of individuals later found to be ineligible. This is similar to the Medicaid and CHIP programs which offer states their FMAP for expenditures made during the period required to verify documentation and status.

We urge OCIIO to add a new provision, § 152.15(a)(4), as follows:

(4) When a PCIP submits the name and social security number of an individual to the Commissioner of Social Security or Department of Homeland Security, as applicable, or an applicant provides documentation of the individual's citizenship, nationality, or lawful presence, the following requirements apply:

(i) if the PCIP receives notice from the Commissioner of Social Security or Secretary of Homeland Security, as applicable, that the name or social security number of the individual is invalid –

(A) the PCIP makes a reasonable effort to identify and address the causes of such invalid match, including through typographical or other clerical errors, by contacting the individual to confirm the accuracy of the name or social security number, respectively, submitted, and by taking such additional actions as the Secretary, through regulation or other guidance, or the State may identify, and continues to provide the individual with PCIP benefits while making such effort; and

(B) in the case that the name or social security number of the individual remains invalid after such reasonable efforts, the PCIP --

(I) notifies the individual of such fact;

(II) provides the individual with a period of 90 days from the date on which the notice required under subclause (I) is received by the individual to either present satisfactory documentary evidence of citizenship or nationality or cure the invalid determination with the Commissioner of Social Security or Secretary of Homeland Security (and continues to provide the individual with PCIP benefits during such 90-day period); and

(III) disenrolls the individual from the PCIP under this title within 30 days after the end of such 90-day period if no such documentary evidence is presented or if such invalid determination is not cured.

(ii) if the PCIP has reasonable cause to believe the documentation provided by the individual is invalid –

(A) the PCIP makes a reasonable effort to identify and address the causes of such invalid match with the individual, including through typographical or other clerical errors, by contacting the individual to confirm the accuracy of the documentation submitted, and by taking such additional actions as the Secretary, through regulation or other guidance, or the State may identify, and continues to provide the individual with PCIP benefits while making such effort; and

(B) in the case that the documentation remains invalid after such reasonable efforts, the PCIP --

(I) notifies the individual of such fact;
(II) provides the individual with a period of 90 days from the date on which the notice required under subclause (I) is received by the individual to either present satisfactory documentary evidence of citizenship or nationality or cure the invalid determination with the Commissioner of Social Security or Secretary of Homeland Security (and continues to provide the individual with PCIP benefits during such 90-day period); and
(III) disenrolls the individual from the PCIP under this title within 30 days after the end of such 90-day period if no such documentary evidence is presented or if such invalid determination is not cured.

§159.19(a): Covered Benefits

Section 152.19(a) states that the PCIP shall cover certain services. In the preamble, it was explained that although the list of required services had yet to be issued, required services would be consistent with the most commonly covered services in already existing high risk pools. However, without greater clarification of the concrete services provided to individuals, it is impossible to ensure that individuals will receive necessary medical care through the PCIP.

We urge OCIIO to promulgate final rules that require the PCIP to cover comprehensive preventive care services and maternity care, including comprehensive contraceptive devices and services and prenatal counseling. We also recommend that the services provided in a PCIP reflect the same essential health benefit requirements included in PPACA §1302(b) and the interim final rules for group health plans and health insurance insurers relating to coverage of preventive services (OCIIO-9992-IFC).[14] Further, language services should be provided in conjunction with covered services so that LEP individuals can fully understand and appreciate the services available to them through the PCIP.

Recommendation 1: Preventive Care Should Include Comprehensive Contraception Services

The importance of women's ability to prevent pregnancy is well established within medical guidelines across a range of practice areas for many reasons. Most pertinent to this regulation, contraception helps prevent unwanted pregnancy for those women with chronic diseases who wish to not become pregnant for fear that pregnancy will compromise their health or the health of the fetus. For women with chronic diseases, such as diabetes, epilepsy, depression, lupus or some forms of cardiovascular disease, pregnancy may worsen the woman's condition. In addition, drug course treatments for these diseases may cause severe fetal impairments.[15] For these women, failure to obtain contraceptive services may result in serious, adverse medical consequences, both to the woman and the fetus.

14 Interim Final Rules for Group Health Plans & Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection & Affordable Care Act, 75 F.R. 137, 41741-53 (Jul. 19, 2010).

15 The CDC reports that three percent of women who could potentially become pregnant are taking teratogens, drugs known to cause serious fetal impairments and abnormalities. CDC, *Recommendations to improve preconception health and health care – United States: a report of the CDC/ATSDR Preconception Care Work Group and Select Panel on Preconception Care*, MORBIDITY & MORTALITY WEEKLY REPORT, (CDC, Atlanta, Ga.), April 21, 2006, at 1-23.

In addition, there are many numerous negative health effects of unwanted pregnancy. Unwanted pregnancy is associated with maternal morbidity and risky health behaviors, as well as low-birth weight babies and insufficient prenatal care.[16] The American College of Obstetricians and Gynecologists (ACOG) notes that women who become pregnant less than six months after their previous pregnancy are 70 percent more likely to have membranes rupture permanently and are at significantly higher risk of other complications.[17] Children born from wanted pregnancies also tend to be healthier than those born from unwanted pregnancies.[18] Women with unintended pregnancies are less likely to seek adequate prenatal care, if at all, and thus risk a greater chance of complications during pregnancy and birth. Without adequate prenatal care, there is greater risk of unchecked fetal abnormalities and decline in fetal health.[19]

We urge OCIIO to add to § 152.19(a) a new subparagraph (15) as follows:

> ***(15) Comprehensive contraception services including all FDA-approved contraceptive drugs and devices.***

> *Recommendation 2: Maternity Care Should Include Prenatal Counseling*

Prenatal counseling is one of the best ways to ensure healthy pregnancy and birth, as it allows a pregnant woman (or a woman seeking to become pregnant) to have access to ongoing medical care in her pregnancy. According to the National Institutes of Health, "[p]renatal healthcare is more than just healthcare; it often includes education and counseling about how to handle different aspects of pregnancy, such as nutrition and physical activity, what to expect from birth itself, and basic skills for caring for your infant."[20]

Pregnant women who undergo prenatal counseling are able to have their pregnancies assessed on a regular basis for any complications. Such complications that could arise include fetal abnormalities, decline of fetal development and/or health, and decline in the woman's health. Catching these complications early in the pregnancy could reduce further complications to the pregnancy or the fetus, and could also help a pregnant woman choose which course of medical treatment is best for her well being.

Additionally, prenatal counseling provides pregnant women (or women who wish to become pregnant) who have existing medical problems ongoing assessments of the risks associated with pregnancy. For instance, obesity during pregnancy can lead to gestational hypertension, diabetes and Cesarean delivery, as well as increase the likelihood that the infant will be obese, have diabetes and be born with congenital

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16 S.S. Brown & L. Eisenberg, *Institute of Medicine Committee on Unintended Pregnancy: The best intentions: unintended pregnancy and the well-being of children and families*, National Academy Press (1995).

17 Am. Coll. of Obstetricians & Gynecologists, *State of the American College of Obstetricians and Gynecologists: Safe Motherhood* (2002).

18 WHO, *Make every mother and child count*, WORLD HEALTH REPORT (WHO, Geneva, Switz.) (2005), *available at* http://www.who.int/whr/2005/whr2005_en.pdf (last visited Sept. 17, 2010).

19 Eunice Kennedy Shriver Nat'l Inst. of Child Health & Human Development, *Care Before & During Pregnancy – Prenatal Care*, http://www.nichd.nih.gov/womenshealth/research/pregbirth/prenatal_care.cfm (last visited Sept. 15, 2010).

20 Eunice Kennedy Shriver Nat'l Inst. of Child Health & Human Development, Care Before & During Pregnancy – Prenatal Care, http://www.nichd.nih.gov/womenshealth/research/pregbirth/prenatal_care.cfm (last visited Sept. 15, 2010).

heart defects.[21] For women with existing medical problems, early discussions with a physician about how pregnancy will impact their health increases patient education and awareness, early detection of problems and helps prevent further complications.

We urge OCIIO to amend § 152.19(a)(14) to read as follows:

(14) Maternity care ***(including prenatal counseling)***

Recommendation 3: Covered Services Should, at a Minimum, Include the Required Services in PPACA §1302 and OCIIO-9992-IFC (Coverage of Preventive Services for Group Health Plans and Health Issuers)

PPACA §1302(b) explicitly requires health plans to cover certain required services.[22] While § 152.19(a) of the Rules provide similar services, there is no reason why the Rules should not reflect the exact same services in PPACA §1302(b). Reflecting the same language in PPACA §1302(b) will only provide consistency with the statute, but will also ensure that the minimal services required in general health care plans be extended to those individuals in the PCIP program. It is only reasonable that individuals in the PCIP be able to access the same services available to the general public through the exchanges.

We urge OCIIO to amend § 152.19(a) to read as follows:

(3) Mental health and substance abuse services***, including behavioral health treatment***;

(8) Diagnostic x-rays and laboratory tests ***and laboratory services***;

(9) Physical therapy services (occupational therapy, physical therapy, speech therapy) ***and rehabilitative and habilitative services and devices***;

(13) Preventive care ***and wellness services and chronic disease management***;

(14) Maternity ***and newborn*** care ***(including prenatal counseling)***

In addition, § 152.19(a)(13), which requires coverage of preventive care, should, *at a minimum*, include the provided preventive care services required for group health plans in a recently promulgated interim final rule by this Department, OCIIO-9992-IFC.[23] These preventive services include a wide array of health services for all individuals, as well as important and vital health services for women, and could be especially integral to managing the care of those with pre-existing conditions.

Recommendation 4: Include Language Services in Conjunction with all Covered Benefits

21 Dr. J. Mills, *Risk of Newborn Heart Defects Increases with Maternal Obesity*, (Eunice Kennedy Shriver Nat'l Inst. of Child Health & Human Development, Rockville, Md.), http://www.nichd.nih.gov/news/resources/links/transcript040710.cfm (last visited Sept. 15, 2010).

22 Pub. L. No. 111-148, 111-152.

23 Interim Final Rules for Group Health Plans & Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection & Affordable Care Act, 75 F.R. 137, 41741-53 (Jul. 19, 2010); see also NHeLP's comment on OCIIO-9992-IFC, *available at* http://www.healthlaw.org/index.php?option=com_content&view=article&id=456:health-reform&catid=51&Itemid=212 (last visited Sept. 28, 2010).

Language services must be provided in conjunction with benefits covered by the PCIP. As explained earlier in this comment, language services are integral to PPACA § 1557 and Title VI, both of which apply to PCIP since it is a federally-funded program. To best provide medical care, it is essential that medical providers and patients/enrollees be able to communicate about health care with one another, and that enrollees be able to understand and appreciate the services available for them through the PCIP. This includes meaningful access for all non-English speaking enrollees through competent oral interpreters or competent bilingual staff where oral language services are needed.

OCIIO should clarify that there is a separate requirement regarding oral communication, notwithstanding requirements for translating written vital documents. As explained earlier, these services are recognized by the HHS LEP Guidance which clarifies the requirements to provide oral communication that is separate and distinct from translating written documents.

We urge OCIIO to add to § 152.19 new subparagraph (a)(15) as follows:

(15) Language Services, when provided to a limited English proficient individual in connection with the provision of a service enumerated in subparagraphs (1) through (14).

Finally, it is critical to specify that an LEP individual may not be charged any co-pays or cost-sharing for language services. This complies with Title VI and the HHS LEP Guidance.

§152.19(b): Excluded Services

Recommendation: Delete § 152.19(b)(4)

Section 152.19(b) adds abortion to the list of excluded services, with exceptions only for when the life of the woman would be endangered or when the pregnancy is a result of rape or incest. We urge the Secretary to remove this exclusion.

A recent Commonwealth Fund report estimates that 38% of women trying to purchase health insurance in the individual market from date to date were either denied, were charged a higher premium, or faced an exclusion based on a pre-existing condition.[24] Many women suffer from chronic conditions which could be significantly exacerbated by pregnancy. Standard medical practice and accepted guidelines recommend that women with conditions such as lupus, severe cardiovascular disease, multiple sclerosis and other health challenges be offered the opportunity to terminate pregnancies that may put their health at risk.[25] These women may also be likely to have been prescribed drugs that are extremely harmful to a developing fetus.[26] These are exactly the women who have been excluded from insurance coverage and

24 S. R. Collins, S. D. Rustgi & M. M. Doty, *Realizing Health Reform's Potential: Women and the Affordable Care Act of 2010,* Commonwealth Fund (2010), available at http://www.commonwealthfund.org/~/media/Files/Publications/Issue%20Brief/2010/Jul/1429_Collins_Women_ACA_brief.pdf (last visited Sept. 27, 2010).

25 *See, e.g.,* European Society of Cardiology Expert Task Force on the Management of Cardiovascular Diseases During Pregnancy, *Consensus Document on Management of Cardiovascular Diseases During Pregnancy*, 24 EUROPEAN HEART J. 761-81 (2003) (recommending that for some high risk patients, "Pregnancy is not recommended. If pregnancy occurs, termination should be advised as the risks to the mother are high (mortality 8-35%, morbidity 50%).

26 E. Bimla Schwartz et al., *Prescription of Teratogenic Medications in United States Ambulatory Practices*, 118 AM. J. OF

whom the Pre-Existing Condition Insurance Plan Program is intended to serve. Removing a critical health service from these women undermines the goals of the PCIP, and puts women at further risk.

Neither § 1101 nor the President's Executive Order of March 24, 2010[27] requires the proposed limits on abortion coverage in the PCIP. Section 1101 is silent on abortion. The President's Executive Order refers to the Hyde Amendment, but the Hyde Amendment is an appropriations rider that has been attached to the Labor, Health and Human Services Appropriations Act annually.[28] By contrast, § 1101 separately appropriates funding for the PCIP and is not impacted by the Hyde Amendment. Moreover, the Background section of the proposed regulation states that the PCIP is "similar" to the Federal Employees Health Benefit Plan (FEHB), and therefore the same abortion restrictions should apply. There are significant distinctions between the PCIP and the FEHB, and therefore the FEHB restrictions should not apply. First, the abortion restrictions in the FEHB are enacted in a separate appropriations provision specific to the FEHB.[29] § 1101 is silent on abortion and contains no such specific restriction. Second, the PCIP is very different from the FEHB. PCIP enrollees are not federal employees, they will be paying significant premiums and co-pays out of their own pockets, and, as noted in the Background to the proposed PCIP regulations, it is estimated that 45% of the funds in the PCIP will be paid by the enrollees. These women should not be prohibited from accessing needed abortions services in private insurance for which they have paid with their own funds.

The PPACA allows states to determine if abortion will be covered in plans that participate in the exchanges, and HHS should allow PCIPs to determine whether to cover abortion services in their plans.

§ 152.21: Premiums and Cost Sharing

Recommendation 1: Cost-sharing for Language Services Should be Prohibited

We urge OCIIO to add to § 152.21 new subparagraph (c) as follows:

(c) Prohibition on cost-sharing for language services. A PCIP may not charge an applicant or enrollee any cost-sharing or co-pays for any language services.

Recommendation 2: The Ban on Gender Rating Should be Extended to These Regulations

Pursuant to PPACA § 1101(c)(2)(C), referencing the language in § 2701(a), gender may not be a factor in setting premium costs for qualified high risk insurance pools. Rather, premiums may only be based on age, tobacco use and family or individual status. Moreover, PPACA § 1557 forbids discrimination in any health plan or activity. We urge OCIIO to follow these provisions in PPACA and ensure exclusion of gender rating from PCIP premiums and cost-sharing.

§ 152.22 Access to Services

MEDICINE 1240-49 (2005).

27 Ensuring Enforcement and Implementation of Abortion Restrictions in the Patient Protection and Affordable Care Act, Exec. Order No. 13, 535, Fed. Reg. 15, 599 (Mar. 24, 2010), *available at* http://www.whitehouse.gov/the-press-office/executive-order-patient-protection-and-affordable-care-acts-consistency-with-longst (last visited Sept. 27, 2010).

28 Civil Rights Act of 1964, Pub. L. 111-117 § 507-508; 123 Stat. 3034, 3280 (2009)

29 *Id*. at § 613-614.

We support the proposed regulation requirement that PCIPs must demonstrate it has a sufficient number and range of providers to meet the needs of enrollees. A 2009 report by the Commonwealth Fund explained that aside from discrimination against pre-existing conditions, individuals with pre-existing conditions did not purchase insurance because the plan did not cover services that met their health care needs.[30] We therefore encourage HHS to vigorously enforce this provision.

This provision is especially important with regard to comprehensive reproductive health services as noted in these comments. The determination of whether a PCIP program has a sufficient range of providers should take into consideration the fact that many religiously-controlled hospitals and clinics do not provide a full range of reproductive health services needed by women enrolled in PCIPs. In addition, individual provider refusals may also limit access to care. The provider network should also include essential community providers with expertise in women's health.

Moreover, in the event that an enrollee is not able to access the reproductive health services that she needs within the network, in particular due to provider religious or moral objections, HHS should require the PCIP to allow the woman to access services out of network without penalty.

In addition, a new section § 152.22(b) should be added to ensure that emergency services can be obtained out of network if the services are not available due to a provider religious or moral objection.

§ 152.26 Appeals Procedure

Recommendation 1: Language Services Should be Provided Throughout the Entire Appeals Process

Pursuant to PPACA § 1557 and Title VI, information about the appeals process should, at a minimum, be made available to LEP individuals and should be provided during the appeals process to ensure LEP individual can fully engage and participate in the full appeals process.

Additionally, information and explanation of the appeal process should also be made easily understandable for those with low literacy levels. Similar to making language services available to LEP populations to ensure proper understanding of their rights to appeal, it is additionally necessary to ensure that those with low literacy can obtain information about their rights under the PCIP program.

Recommendation 2: The Appeals Process Should Adopt the Same Minimum Standards Required in OCIIO-993-IFC (Claims and Appeals and External Review Process for Group Health Plans and Issuers)

The appeals process, at a minimum, should adopt the articulated minimal standards for appeals in group health plans, as promulgated in the interim final rule, OCIIO-993-IFC.[31] In the preamble of these PCIP

30 M. Doty, et al., *Failure to Protect: Why the Individual Insurance Market is Not a Viable Option for Most U.S. Families*, The Commonwealth Fund (2009), *available at* http://www.commonwealthfund.org/Content/Publications/Issue-Briefs/2009/Jul/Failure-to-Protect.aspx (further explaining that the other reason individuals did not purchase insurance was because of discrimination against their pre-existing condition).

31 Interim Final Rule for Claims and Appeals and External Review Process for Group Health Plans and Issuers, 75 Fed.

regulations, it was reasoned that a fully articulated appeals process was not needed both because PCIP is temporary and because it is believed that States' existing appeals/review mechanisms are sufficient and subject to the Secretary's approval. However, considering the appeals process for group health plans will be in effect starting July 1, 2011, it is more reasonable to require PCIPs to follow the appeal process required in OCIIO-993-IFC once the final rules are promulgated. Requiring PCIPs and group health plans to provide enrollees with the same review mechanism not only ensures consistency in regulations, but also provides the same administrative benefits and services to PCIP enrollees as to enrollees in general group health plans.

CONCLUSION

NHeLP looks forward to working with OCIIO on the implementation of the interim final rules for the pre-existing condition insurance plan program. 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

Reg. 141, 43359-63 (Jul. 23, 2010); *see also* NHeLP's comment on OCIIO-993-IFC, *available at* http://www.healthlaw.org/index.php?option=com_content&view=article&id=456:health-reform&catid=51&Itemid=212 (last visited Sept. 28, 2010).