March 18, 2014

By email: FFEcomments@cms.hhs.gov
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Comments on 2015 Letter to Issuers in the Federally-facilitated Marketplace (FFM)

Dear Sir/Madam:

The National Health Law Program (NHeLP) is a public interest law firm working to advance access to quality health care and protect the legal rights of low-income and underserved people. We appreciate the opportunity to provide comments in response to the 2015 Letter to Issuers in the Federally-facilitated Marketplace.

Chapter 2. Qualified Health Plan and Stand-alone Dental Plan Certification Standards

Section 1. Licensure and Good Standing

HHS indicates that "[i]n addition to requiring state certification of good standing, CMS will consider complaints and other QHP issuer oversight findings that occur during the 2014 benefit year in its determination of whether an issuer's offering of a plan is in the interest of consumers." HHS will only be able to meaningfully use consumer complaints (and commendations) if consumers have notice and an accessible way to provide complaints, and HHS has a well develop system for compiling and analyzing the complaints (including, for example, identifying issues impacting demographic or health status sub-populations).

Section 2. Service Area

HHS' discussion of service areas identifies situations where a plan might cover less than an entire county (or group of counties) or change its service area after plan data submission. We believe that the "best interest of the consumer" standard on page 18 will rarely favor covering only part of a county or allowing service area changes. We recommend HHS develop stronger limiting standards

for these flexibilities, since they will allow plans to avoid covering subpopulations who most need access to care in the first place.

Section 3. Network Adequacy

We appreciate HHS' concerns with and efforts to address network adequacy and we are generally supportive of the proposal to pay special attention to historically problematic areas. We assume, first, that this effort is *in addition* to an exhaustive review of the entire provider list. Second, counting numbers and types of providers is insufficient to determine if all covered services are functionally available within the network. This is a particular concern for reproductive health services. Various health care refusal laws (also known as conscience clauses) may allow hospitals and individual providers to refuse to provide covered reproductive health services. Therefore, a mere count of numbers of hospitals or numbers of Ob/Gyns will not be an adequate reflection of network adequacy. We recommend that at a minimum the entire list must be reviewed for breadth of provider network (sufficient types of providers), documentation of whether covered services are actually available without delay (provision of covered services), capacity proportions (number of providers per population), travel distances (geo-mapping), waiting times, and access to essential community providers (discussed more later). This evaluation should not count providers who are "in-network" but not accepting new patients. In terms of covered reproductive health services, it should not count hospitals, clinics, and providers who refuse to provide a full range of covered reproductive health services.

Finally, QHPs must be required to allow an individual to obtain a covered service from an out-of-network provider at no additional cost if no network provider is accessible for that service in a timely manner. Furthermore, QHPs should include in their applications a description of their procedures for approving out-of-network care as well as specialty care and be required to describe those procedures in all consumer information. CMS must review those procedures to ensure they will not impede consumers' timely and appropriate access to out-of-network and specialty care. Last, QHPs must have a transparent process for ensuring timely access to sensitive services when a primary care provider refuses to make a referral.

To the extent HHS pays extra attention to historically problematic areas, we agree that hospitals and mental health, oncology, and primary care providers are important areas of focus, but we encourage HHS to consider many other specialty areas that are often access problems. Within primary care and specialty fields, sub-specialized providers (for example, pediatric neurologists, infectious disease HIV specialists, family planning providers, and abortion providers including hospital-based abortions when abortion is a covered service) are even more problematic. Meaningful analysis of network adequacy requires granular provider capacity, not just a raw number of providers within a broad category (such as primary care).

In addition to sharing network adequacy finding with states, we urge HHS to publicly report the findings. We commend the suggestion of "appropriate formats for collection of

this data which would enable creation of a search engine function for consumers to search for particular providers and provider types" on page 20.

Section 4. Essential Community Providers

We appreciate that CMS intends to propose rule-making to evaluate "sufficient inclusion of ECPs for the 2015 benefit year." We have several concerns with the policy under consideration.

First, we believe HHS should further increase the 2015 standard beyond 30% of providers. We believe the long-term goal should be for QHPs to include a substantial majority of ECP infrastructure in their networks.

Second, while we recognize that HHS has made an effort to address diversity of ECP providers by at least requiring one contractual offer in each ECP category, this is insufficient to meet the health needs of vulnerable populations. We believe QHPs should be required to include at least two providers of each category in their network. This standard itself should be subject to distance/waiting time analysis, and QHPs should have to add providers if they fall below a certain ECP access threshold in each category. This standard should be increased in subsequent years.

Third, we are concerned about the language "without further documentation" on page 20. We believe QHPs must document their compliance. We are also concerned about the proposal that would allow QHPs to "justify" their failure to meet the 2015 ECP requirements. We believe that QHPs should be required to comply with the 2015 standards. The only acceptable "justification" should be in areas where an insufficient number of ECPs are located.

Fourth, we do not believe that QHPs should be permitted to include less than two providers in each category (as suggested above), and thus disagree with exceptions ("justification") process allowed for non-compliance. An exception should only be created in situations where there are not two available ECPs in a specific category.

Chapter 3. Qualified Health Plan and Stand-alone Dental Plan Design

Section 1. Discriminatory Benefit Design: 2015 Approach

In all of our prior comments on the EHB standard we consistently raised the concern that, if given too much flexibility, some issuers might use benefit design in a discriminatory way. There is some clear evidence this is happening exactly as we warned it would. While we agree there is an important state role to play in enforcing non-discrimination, and we appreciate the requirement for plans to file non-discrimination attestations, we consider it essential that HHS take an active role in monitoring and analyzing benefit design for discriminatory impact.

HHs indicates it will conduct "outlier" analysis to identify problems. We support the use of outlier analysis. However, given that discrimination is often based on long-standing and pervasive benefit design customs in the insurance industry, looking for outliers is not enough. We believe that there must also be analysis based on concrete clinical standards (for example, does the benefits package allow for the adequate treatment of a specific mental health condition?). HHS must have a role in evaluating the benefits package based on established clinical protocols.

When outlier analysis is used *in addition* to clinical standards, it may be effective if the level of analysis is sufficiently deep to identify discriminatory practices. For example, analysis of an issuer's status as an outlier on all prescription drug coverage may provide valuable information about an issuer's broad coverage deficiencies. But such an aggregated level of analysis may not be able to identify an issuer who discriminates against individuals with HIV by reducing access to HIV-specific prescription drugs. Thus, while we believe HHS has suggested five good benefit areas for analysis, the analysis will need to be much more granular to be useful for non-discrimination enforcement.

Finally, we believe that the range of analysis will need to also be broad. In addition to looking at the covered benefits in any given plan, HHS will need to scrutinize the applicable cost-sharing, prior authorization requirements, formulary tiers, step therapies, quantity limits, and other utilization management protocols which may be used to create a discriminatory effect.

Section 2. Prescription Drugs

We urge HHS to review and strengthen policies implementing 45 C.F.R. 147.200(a)(2)(i)(K). Accurate formulary information has historically been a consistent problem for consumers struggling to evaluate managed care benefits, and we have already heard reports of inaccurate formulary information in the Marketplace. Plans should be required to have one formulary which is up-to-date, and consumers should not get a different version of the formulary when they contact the Marketplace or the plan itself. The information in the formulary should be presented in a consistent way, and provide the consumer with all of the information needed to make a plan selection, including factors such as prior authorization criteria, step therapies, and enough cost-sharing information to assess the actual cost of treatment. (See also 45 C.F.R. 156.220(d)).

We are strongly supportive of the suggestion on page 33 to "propose through rulemaking that Marketplaces may require that issuers temporarily cover non-formulary drugs, including drugs that are on the issuer's formulary but require prior authorization or step therapy, as if they were on the issuer's formulary during the first 30 days of coverage." In fact, we would suggest that HHS work towards making this policy (1) a requirement for all Marketplaces, and (2) amend the "first 30 days of coverage" requirement to a requirement to "the full course of that treatment."

Section 3. Supporting Informed Consumer Choice

Like all consumer advocacy organizations, we are strong proponents of consumer choice. However, choice can also be used to confuse consumers, and thus HHS should prioritize *meaningful* choices. We therefore urge HHS to be reserved in setting plan variation flexibility standards, approving plan variations based on those standards, and most particularly, allowing exceptions to plans that exceed the flexibility standards.

Section 7. Coverage of Primary Care: 2015 Approach

We are supportive of the suggestion that HHS might "require through rulemaking that all plans, or at least one plan at each metal level per issuer, cover three primary care office visits prior to meeting any deductible" on page 38. We believe such a policy would have a very positive impact on access to preventive care.

Chapter 4. Qualified Health Plan Performance and Oversight

Section 3. QHP Issuer Compliance Reviews

We recommend that, particularly in the first years of Marketplace function, HHS perform more than a "limited number of compliance reviews." In the early years of Marketplace function plans may lack infrastructure or institutional knowledge, rules may be unclear or insufficient, and numerous technical problems may arise, and thus it will be important for HHS to conduct a lot of compliance reviews to ascertain the scope and prevalence of problems.

Section 5. Monitoring of Marketing Activities

We believe HHS should have a role in supplementing marketing monitoring in all states, not merely ones "where there is no or minimal review of QHP marketing materials."

Chapter 6. Consumer Support and Related Issues

Section 1. Provider Directory

As per our suggestions above regarding formularies, we urge HHS to review and strengthen policies requiring plans to have accurate provider directories. Accurate provider lists have historically been a consistent problem for consumers struggling to evaluate managed care networks, and accurate in-network provider lists are probably the single most important criteria consumers may need to select a plan. In particular, plans have historically failed to regularly update their provider lists, both in terms of how frequently the information is reviewed and how carefully the plan updates its website, call center, and in this case, the Marketplace website and call center. Finally, the provider lists must also provide up to date information on whether a provider is accepting new patients, and whether the provider offers all covered services that would

normally be expected from the type of provider, as these have been historical problems for consumers selecting or using a managed care plan.

We support the encouragement of including the languages spoken in provider directories. We suggest that issuers ensure that any provider that includes a language spoken by the provider or his/her staff have sufficient language competency in that language. Effective communication depends on actual language proficiency and competency. If a member of the provider's staff has the language competency and is going to interpret for the patient and provider, the staff person must have sufficient knowledge, skills and training as an interpreter. According to the HHS Office for Civil Rights in its "LEP Guidance," being bilingual alone is not sufficient to interpret. Thus, if a provider is going to list the languages spoken in the office, the QHP should ensure the language skills are sufficient so an LEP individual who selects that provider can be able to effectively communicate. We also encourage QHPs to designate who in the provider's office—the provider or his/her staff—could provide services directly in the non-English language and serve as interpreters. The QHP could require language testing for providers as a pre-condition for listing a language in the provider directory and interpreter training if a provider will use bilingual staff to communicate with LEP patients.

Section 2. Complaints Tracking and Resolution

We believe it is absolutely critical that HHS develop a comprehensive system to compile and evaluate consumer complaints *and* coverage appeals. We recommend that HHS require each plan to describe in writing how it will comply with "all applicable state and federal laws related to consumer complaints, including any applicable requirement to advise consumers of their appeal rights" (page 48) and the requirements of 45 C.F.R. 147.136. It is not enough for HHS to simple require compliance. A documented system will allow all parties – plans, consumers, HHS, and consumer advocates – to identify and help correct problems.

Equally importantly, HHS must take an active role in tracking complaints and their resolution. This analysis should include granular review of complaints and outcomes for sub-populations based on demographic factors and health status. HHS should also publicly post its findings and remedial activities.

Section 3. Coverage Appeals

See section 2 above.

Section 4. Meaningful Access

We appreciate the Letter's references to the Enhanced National CLAS Standards, the non-discrimination protections of Title VI of the Civil Rights Act of 1964, and Section 1557 of the ACA.

However, we are deeply concerned that the Letter continues to punt on the issue of regulatory guidance clarifying the scope of protections for LEP individuals and the standards for ensuring QHP issuers are providing meaningful access. The Letter fails to provide sufficient information to issuers to understand the depth and breadth of assistance they must provide. We strongly believe specific, detailed requirements are necessary as individual health and lives are at stake when they are accessing health care services, and must be able to actively participate and communicate with their insurers and health care providers.

We understand that CMS does not wish to solicit comments on underlying policies that will be subject to future rulemaking, however we feel that the application of existing non-discrimination protections and the challenges many LEP consumers are currently facing in the marketplace enrollment process warrant the swift adoption of specific and detailed standards in the Letter. Therefore, we urge CMS to expeditiously issue meaningful access standards for LEP individuals and people with disabilities. We also urge CMS to promulgate regulations on Section 1557, which are referenced in the Letter yet continue to lack the necessary regulatory guidance for issuers or other stakeholders to ensure their robust application.

As such, we recommend CMS provide specific examples on how QHP issuers can satisfy meaningful access standards. For example, with regard to language access, include a paragraph such as the following:

> "To assist QHP issuers in complying with the standards established in 45 C.F.R. §§ 155.205(c), 155.230(b), and 156.250, we have outlined the following measures, which are evidence of compliance with the regulatory requirements established by 45 C.F.R. §§ 155.205(c), 155.230(b), and 156.250.
>
> Language Access:
>
> - Applications and notices, as described in the list below, produced or used by QHP issuers should be available in the languages spoken by the state's top ten largest LEP groups or spoken by 10,000 persons or greater, whichever yields the greater number of languages. These applications and notices should also include taglines in the top 30 non-English languages in the state indicating the availability of free language assistance services through a QHP issuer's call center.
>
> - QHP issuers should offer oral interpretation, such as through telephonic interpreter services via a call center, in 150 languages, for notices and applications.

- QHP issuer Websites that contain information about QHPs, including applications and notices, should have taglines in the top 15 non-English languages in the state indicating the availability of free language assistance services through a QHP issuer's call center. Websites with content in English should be translated into Spanish, and applications and notices appearing on issuer Websites should meet the standards above."

We support the Letter's inclusion of a minimum list of forms and notices, including the single streamlined application, as essential documents necessary to ensure meaningful access. We note, however, that a federal recipient may fulfill its obligation of providing meaningful access under Title VI by translating all *vital* documents. Although the Letter refers to these as *essential* documents, it provides a non-exhaustive list of the sort of document that would fall into this category – a list that appears consistent with current HHS LEP Guidance.[1] HHS also recognizes that vital documents include not just those used during the receipt of medical care but also materials that raise "[a]wareness of rights or services" such that "where a recipient is engaged in community outreach activities, it should regularly assess the needs of the populations frequently encountered or affected by the program or activity to determine whether certain critical outreach materials may be the most useful to translate."[2] When the consequence of information is a person's access to a program or activity, whether through awareness or actual application, these materials should be considered vital documents.

Section 5. Summary of Benefits and Coverage

Section § 1303 of the ACA requires issuers to include in the Summary of Benefits and Coverage information regarding abortion coverage. To date, there is no clear guidance to issuers on how that information should be provided. The ACA requires that every SBC include a table of common medical events with coverage descriptions of typical health services related to these medical events. Abortion is a very common medical event – one out of three women will have an abortion in her lifetime. CMS should require that issuers include abortion in the table of common medical events under basic health services. The issuer should be directed to detail any limitations, exclusions, or other conditions under which abortion services are covered and provided.

Section 6. Transparency

[1] HHS LEP Guidance, 68 Fed. Reg. at 47,318; LEP.gov, Frequently Asked Questions (listing as vital documents: "applications, consent and complaint forms; notices of rights and disciplinary action; notices advising LEP persons of the availability of free language assistance; prison rulebooks; written tests that do not assess English language competency, but rather competency for a particular license, job, or skill for which English competency is not required; and letters or notices that require a response from the beneficiary or client"); HHS LEP Guidance, 68 Fed. Reg. at 47,319 (listing as possible vital written materials: consent and complaint forms; intake forms; notices, written tests that do not assess English language competency; applications to participate in a recipient's programs or activities; hospital menus; third party documents, forms, or pamphlets; government documents and forms; and general information)
[2] HHS LEP Guidance, 68 Fed. Reg. at 47,318.

We strongly support the development of future guidance to address transparency requirements as required by 45 C.F.R. 156.220. We consider it essential that HHS collect robust information about topics in this regulation such as enrollment, disenrollment, claim denials, and out-of-network cost-sharing policies. We also urge HHS to make all of the information fully accessible to the public as required under subsection (b).

Conclusion

Thank you for the opportunity to provide comments on the 2015 Letter to Issuers in the FFM. If you have any questions regarding our comments, please contact Leonardo Cuello (cuello@healthlaw.org) at the National Health Law Program.

Sincerely,

/s/

Emily Spitzer
Executive Director