January 12, 2015

Kevin Counihan
Deputy Administrator and Director
Center for Consumer Information and Insurance Oversight
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave. S.E.
Washington, DC

RE: **DRAFT 2016 Letter to Issuers in the Federally-facilitated Marketplaces**

Dear Deputy Administrator Counihan,

Thank you for opportunity to comment on the Draft 2016 Letter to Issuers. The National Health Law Program (NHeLP) protects and advances the health rights of low income and underserved individuals. The oldest non-profit of its kind, NHeLP advocates, educates and litigates at the federal and state level.

We recently provided detailed comments on many of the issues included in the Draft Letter in our comments to the November 2014 Proposed Notice of Benefits and Payment Parameters regulations.[1] We ask that you review these comments in regard to the relevant parts of the Draft Letter while we provide additional specific comments to the letter below.

Chapter 2: Qualified Health Plan and Stand-Alone Dental Plan Certification Standards

Section 3. Network Adequacy

i. Network Adequacy Standard

We commend CMS for continuing to flesh out network adequacy standards for the FFM in its letter to issuers. We especially appreciate that HHS has scrutinized FFM QHPs' provider networks more closely during the most recent QHP certification period,

[1] Letter from Elizabeth G. Taylor, Nat'l Health Law Prog., to Centers for Medicare & Medicaid Servs., Dept. of Health & Human Servs. 28-53 (Dec. 22, 2014), *available at* http://www.healthlaw.org/publications/browse-all-publications/nhelp-comments-notice-of-benefit-and-payment-parameters.

focusing on areas where consumers have historically experienced access problems, including hospital systems, mental health providers, oncology providers, and primary care providers. At this writing, we do not yet have the experience with the QHPs certified to participate in the FFM for 2015 coverage to know whether the "reasonable access" standard has been successful in ensuring access. We are disappointed, however, that the proposed 2016 letter to issuers does not contain any precise quantitative standards that would help insurance regulators, consumers, providers, and advocates evaluate what constitutes "reasonable access."

We appreciate that CMS has indicated that more specific standards may be forthcoming. CMS suggests that it may provide additional details in future rulemaking and during the QHP certification/ recertification process. It also notes (as did HHS in the preamble to the proposed payment notice) that it is also tracking the process of the National Association of Insurance Commissioners, which is currently updating its own Network Adequacy Model Act. But, as we describe in our comments to the payment parameters NPRM, there is no compelling reason to wait, and the need for specific standards is urgent for consumers. *See* NHeLP Payment Parameters Comments at 28-30. We urge CMS to set forth specific standards now, in its final letter to issuers.

All stakeholders benefit when the standards are clear and easy to measure. Without measurable standards, neither issuers nor other stakeholders will understand how QHP networks are being evaluated, and when CMS will consider them to be reasonable. And without specific standards, consumers and advocates also will not know whether access problems they experience warrant a complaint to CMS. In our recent comments, we recommended that HHS adopt specific, quantitative standards to measure access in three specific areas: geographic access, timeliness of appointments, and provider ratios. *See* NHeLP Payment Parameters Comments at 32-37. We also urge CMS to adopt these specific standards in this letter to define reasonable access by setting clear minimum standards that ensure consumers have access to needed health care services.

We also urge CMS to consider measuring other forms of access. As suggested in our recent comments, in evaluating whether QHP networks offer reasonable access, CMS should account for access offered to limited-English proficient (LEP) enrollees and those with disabilities. *See* NHeLP Payment Parameters Comments at 40-41. In order for all enrollees to have real access to the care they need, QHP networks must offer appropriate language access services, and offer providers and facilities that are accessible to individuals with disabilities.

Further, we strongly encourage CMS to require QHP issuers in the FFM to provide enrollees access to care from out-of-network providers in certain circumstances. *See* NHeLP Payment Parameters Comments at 37-39. QHP issuers must be required to provide access to care out-of-network when there are no appropriate providers available in-network, including when network providers are not located within a reasonable distance from the enrollee, do not have appointments available within a reasonable amount of time, lack the appropriate expertise, or refuse to provide a needed covered

service. In addition, we urge CMS to require QHP issuers to provide continuity of care with out-of-network providers in situations where consumers have a preexisting treatment relationship with an out-of-network provider. These situations could arise upon enrollment, for example when a consumer's income goes up and she moves from Medicaid into a QHP, or during enrollment, for example when a consumer's provider terminates his contract with a QHP midway through the plan year.

Finally, we urge CMS to set forth its process for monitoring network adequacy in QHPs with particularity. We appreciate that CMS has indicated in the proposed letter that it will use complaint tracking to monitor network adequacy, but provides no explanation of which complaints will be monitored, and how. In our comments to HHS's Proposed Payment Parameters, we urged HHS to require issuers to provide the Exchanges with regular reports of the number of internal and external appeals it received related to network adequacy and timely access, to assist in the monitoring process. We also suggested that HHS require issuers to provide Exchanges with geo-mapping and timely access reports to aid their evaluation of network adequacy. We urge CMS to adopt these methods of monitoring access and, in the final letter, require QHP issuers to provide this information to CMS starting in 2016. Lastly, CMS should take compliance actions against any issuers with QHP networks that CMS finds inadequate. *See* NHeLP Payment Parameters Comments at 41-44.

ii. Provider Directory Links

We strongly support the additional standards regarding provider directories set forth in HHS's Proposed Payment Parameters and adopted in this letter. In our comments to HHS's Proposed Payment Parameters, we urged HHS to require issuers to improve its proposed rules by requiring issuers to do the following:

- Update directories every 15 days, rather than 30;
- Include additional information about providers, such as language spoken, and facility accessibility in their directories;
- Ensure directories explain different network options and the consequence of using a higher tier network providers;
- Publicize a method of reporting directory inaccuracies;
- Audit their networks and directories regularly;
- Reach out to providers that have not submitted recent claims to confirm they are still participating in the plan; and
- Honor the information that is printed in their directories.

See NHeLP Payment Parameters Comments at 44. We suggest that CMS also adopt these improvements in the Letter to Issuers.

And while we support the encouragement of including the languages spoken in provider directories, we suggest 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 4. Essential Community Providers

i. Evaluation of Network Adequacy with Respect to All ECPs

We appreciate CMS's continuing efforts to ensure that QHP networks include essential community providers (ECPs). We understand the approach CMS is taking in this letter to largely reflect the approach set out in HHS's Proposed Payment Parameters last year, which we generally commended. We appreciate that CMS will continue to require issuers to enter contracts with at least 30% of available ECPs in the service area. We encourage CMS to consider increasing the percentage required in future years. We particularly support CMS's clarification that certain family planning providers who do not receive Title X funds qualify as ECPs. *See* NHeLP Payment Parameters Comments at 49-50.

To ensure meaningful access to ECPs, we suggest that CMS further strengthen the ECP requirements set forth in this letter. In our comments to the Proposed Payment Parameters, we urged HHS require issuers to enter, rather than offer, contracts to at least one ECP in each category, to ensure that all consumers have access to all ECP types. We appreciate that CMS is asking issuers to offer contracts in good faith, in recognition of the rare cases where an issuer may not be able to come to agreement with any ECP in a particular category. But we emphasize that these instances should be very rare indeed. At a minimum, CMS should adopt a more stringent definition of "good faith" that accounts for generally applicable reimbursement rates, to ensure that issuers truly take all reasonable efforts to contract with ECPs. For the same reason, we urge CMS to eliminate the option for issuers to provide a narrative justification in lieu of meeting the ECP standard articulated in the letter. We also urge CMS to explicitly adopt provisions to prohibit issuers from discriminating against ECPs based on the services they provide or the population they serve. *See* NHeLP Payment Parameters Comments at 49-52.

Finally, we urge CMS to explain in greater detail in this letter how compliance with the ECP standard will be monitored. We appreciate that CMS has indicated that it will selectively audit issuers that write-in significant numbers of ECPs. We recommend that

CMS adopt other monitoring strategies, and account for access to ECPs whenever it monitors network adequacy in general. *See* NHeLP Payment Parameters Comments at 52.

Section 5. Accreditation

We commend HHS for encouraging QHP issuers to publicly display their accreditation information for consumers seeking health plans through the Exchange. To promote further understanding of the importance of accreditation status, HHS should also provide clear and simple publicly available explanations of the functions of CMS' accrediting entities (e.g., the National Committee for Quality Assurance ("NCQA"), URAC, and the Accreditation Association for Ambulatory Health Care ("AAAHC")) and the meaning of accreditation terms (e.g., "Accredited by NCQA," "Accredited by URAC," and "Not yet accredited," etc.).

Additional explanations of the various types of rankings that NCQA, URAC, and AAAHC provide to QHP issuers, such as, "accredited," "excellent," "commendable," "interim," "full," "provisional," or "conditional" status would assist consumers in selecting QHPs that would better address their health needs and prevent enrollment in unaccredited health plans. Moreover, HHS should ensure that all accreditation explanatory language is available in formats for consumers with low-literacy, limited English proficiency, or disabilities.

The 2016 Letter to Issuers also describes how CMS anticipates continuing to use the 2015 Letter to Issuers' phased approach for accrediting QHP issuers in the FFMs. A recognized accrediting entity (or a commercial or Medicaid health plan accrediting entity) must accredit those QHP issuers entering their second or third year of QHP certification. In contrast, health plan issuers beginning their first year of QHP certification for plan years starting in 2016 ("first year plan issuers") that do not have existing commercial, Medicaid, or Exchange health plan accreditation issued through a recognized accrediting entity are subject to a less stringent requirement. Specifically, the 2016 Letter to Issuers allows first year plan issuers to "schedule or plan to schedule a review of their QHP policies and procedures" with a recognized accrediting entity, instead of obtaining accreditation status as a prerequisite to operating in the Exchange.[2] As a result, first year plan issuers without commercial, Medicaid, or Exchange accreditation could operate in the Exchange for a period of time, without documentation of their accreditation status that indicates the degree of compliance with quality health standards.

If HHS chooses not to require the designation of accreditation status for first year plan issuers, then it should provide public notice that advises consumers seeking coverage in QHPs of the lack of accreditation status for these plans. Without this information, individuals and families may determine their choice of enrollment in health plans based only on their cost, without also knowing the plans' accreditation status.

[2] 45 C.F.R. § 155.1045(b)(1).

RECOMMENDATIONS:

- *Provide publicly available explanations of the purpose of accreditation and relevant terms and rankings*:
    - HHS should provide consumers with clear and concise explanations of the functions of CMS' accrediting entities (e.g., NCQA, URAC, and AAAHC) and the meaning of accreditation terms.
    - HHS should include additional explanations of the various types of rankings that NCQA, URAC, and AAAHC determine for QHP issuers (e.g., "accredited," "excellent," "commendable," "interim," "full," "provisional," or "conditional" status).
- *Provide explanatory accreditation information:* HHS should ensure that all accreditation explanatory language is available in formats for consumers with low-literacy, limited English proficient, or disability needs.

Section 6. Patient Safety Standards for QHP Issuers

The 2016 Letter to Issuers requires certified and re-certified QHP issuers to comply with certain patient safety standards. To do so, QHP issuers that contract with hospitals with more than 50 beds must verify that the hospitals are Medicare-certified or have been given a Medicaid-only CMS Certification Number ("CCN") and are subject to the Medicare Hospital Condition of Participation requirements (for quality assessment and performance improvement and discharge planning).[3] Among other requirements, QHP issuers must also collect and maintain documentation of the CCNs from their network hospitals, and demonstrate compliance with these patient safety standards by attestation for plan years beginning in 2016.

We agree that these requirements will help ensure that QHP issuers comply with important patient safety standards. We further recommend that HHS provide additional transparency of QHP issuers' conformity with these requirements. Specifically, HHS should ensure that documentation of compliance with patient safety standards, as well as a concise explanation of their importance to patient care and well-being should be publicly available to consumers. If QHP issuers contract with hospitals that do not comply with these patient safety standards, this information should also be publicly available to consumers. Patient safety compliance and related information should be provided in formats for consumers with low-literacy, limited English proficiency, or disabilities.

RECOMMENDATION:

- *Transparency of compliance with patient safety standards*:
    - HHS should ensure that documentation of compliance (and lack of compliance) with patient safety standards, as well as a concise explanation of their importance to patient care and well-being should be publicly available to consumers.

[3] *See generally* 42 C.F.R. §§ 488.21, 482.43.

- Patient safety compliance and related information should be provided in formats for consumers with low-literacy, limited English proficiency, or disabilities.

Section 9. Discriminatory Benefit Design

NHeLP applauds HHS for addressing discriminatory plan benefit design in both Essential Health Benefits (EHB) and in Qualified Health Plans (QHPs). As discussed in NHeLP's comments, we strongly urge HHS to rigorously monitor and enforce the ACA's non-discrimination provisions. *See* NHeLP's Payment Parameters comments at 21.

In the 2016 Draft Letter to Issuers, HHS states that "enforcement of this [ACA EHB non-discrimination] standard is largely conducted by states." (2016 Draft Letter to Issuers at 34). We disagree with this approach. HHS should be primarily responsible for monitoring and enforcing federal non-discrimination protections.

We recognize that the ACA provides ample opportunities for state flexibility in some implementation areas. However, that flexibility should not apply to monitoring and enforcing the ACA's non-discrimination provisions designed to protect health care consumers, particularly highly vulnerable individuals living with chronic or disabling medical conditions.

Not all states have been quick to embrace the ACA. Moreover, the lack of clear guidance and coordination has resulted in a patchwork of standards with little or no enforcement of these important non-discrimination protections. We note that a number of 2015 QHPs continue to place all HIV/AIDS medications in the highest cost sharing tier. These plans were approved to participate in the federally facilitated Exchange, despite the clear violation of the ACA's non-discrimination provisions as described by HHS in the preamble to the Payment Parameters rule. In addition, by relying on state monitoring and enforcement of non-discrimination protections, HHS has created the possibility that the same plan benefit design may be considered compliant by one state, but may be found non-compliant by another state.

HHS describes a number of monitoring activities to help determine whether plan benefit designs comply with the ACA requirements including the non-discrimination provisions. We applaud these proposals and urge HHS to employ a broad, multi-pronged approach to non-discrimination compliance monitoring and enforcement.

For example, we support HHS' proposal to conduct outlier analyses for specific conditions examining estimated out-of-pocket costs under recognized treatment guidelines. The five conditions suggested in the Draft Letter – bipolar disorder, diabetes, HIV, rheumatoid arthritis, and schizophrenia – provide a good starting point. However, we are concerned that identifying in advance the conditions to be reviewed may incent plans to adjust their cost sharing structures for these conditions. It would prove more effective to conduct an outlier analysis of additional medical conditions without providing advance notice to issuers.

HHS further states that it will conduct compliance review of plans including examining appeals and complaints (2016 Draft Letter to Issuers, at 35). We strongly support this approach. Consumer complaints and appeals provide on-the-ground perspective of the challenges faced by individuals accessing health care. Complaints and appeals also provide information on plan design and performance in real time. Compliance monitoring and enforcement of federal non-discrimination provisions should be ongoing, and not just one of many issues considered during the annual plan certification process. HHS should make compliance reviews publicly available.

However, neither the 2016 Draft Letter to Issuers nor the Payment Parameters rule indicate how HHS will effectively process and monitor consumer complaints, particularly those complaints concerning non-discrimination and civil rights protections. There are currently multiple entities with overlapping responsibilities to investigate complaints and initiate enforcement actions, including the HHS Office for Civil Rights, the Office of Consumer Information and Insurance Oversight, the HHS Office of the Inspector General, the Centers for Medicare & Medicaid Services, the Department of Justice, as well state insurance regulators and ombuds programs. Accordingly, we urge HHS to clarify its reporting and monitoring process for consumer complaints and appeals.

Section 10. Prescription Drugs

As discussed in NHeLP's comments, we strongly support HHS' proposal to increase formulary and provider transparency so that consumers can select the health plan that best meets their individual health care needs. (See NHeLP's Payment Parameters comments at 20). In addition, we applaud HHS' plan to conduct formulary outlier reviews of plans, and appreciate the recognition that inordinate prior authorization and step therapy requirements may be discriminatory against persons with significant health needs.

However, we urge HHS to not limit its plan reviews and outlier analyses to the annual certification process. As indicated above, we maintain that compliance monitoring and enforcement of the ACA's non-discrimination protections should be ongoing. A discriminatory plan benefit design may not always be detectable during the annual certification process.

In 2014, we received multiple complaints from health care consumers that QHPs modified their prescription drug formularies and cost sharing structures during the course of a plan year. Consumers who selected a QHP specifically because of its formulary and affordability found their drug dropped or the cost sharing increased. An outlier analysis limited to the period of plan certification would fail to detect such discriminatory practices. Therefore, we urge HHS to conduct formulary reviews throughout the plan year.

Chapter 4: Qualified Health Plan Performance and Oversight

Section 3. QHP Compliance Reviews

We applaud HHS for its proposal to conduct compliance reviews of QHPs based largely upon a risk-based process and data collected through its monitoring program. We support the expedited review process to address situations that can be hard for consumers. As indicated above, we urge HHS to make compliance monitoring and review an ongoing process, and not limit such reviews to the time of plan certification.

However, we have serious concerns regarding the lack of transparency in the proposed monitoring and review process. According to the Draft Letter, the results of the review will be shared with the states and issuers. We strongly urge HHS to make the results of its compliance reviews publicly available. Consumers and other stakeholders should be able to review and evaluate for themselves QHP performance based upon HHS' compliance reviews.

Chapter 6: Consumer Support and Related Issues

Section 3. Meaningful Access

As we outlined in our earlier comments, we strongly support the provision in the proposed rule and the Letter to Issuers requiring telephonic language services in at least 150 languages. *See* NHeLP's Payment Parameters comments at 2.

We appreciate the list of essential documents but suggest that CMS explicitly include renewal notices. We also appreciate the recognition that this requirement does not limit or abrogate requirements under Title VI of the Civil Rights Act of 1964 and Section 1557 of the Affordable Care Act.

We also suggest this section include references to the Americans with Disabilities Act and to specifically reference that the same standards apply with regard to access for persons with disabilities who may need alternative formats of these essential documents (such as large print, audio-format or Braille versions).

As we have recommended previously, we believe the Letter to Issuers (and regulations) should more specifically detail the requirements to translate materials in non-English languages. While having oral interpreting telephonic requirements and a list of essential documents are good steps forward, we suggest CMS also include requirements for when these essential documents included in the Draft Letter to Issuers must be translated, because oral communication of technical and complex documents often is challenging and should not negate the need for having translated documents. We recommend that these essential documents 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 documents should also include taglines in the at least 15 non-English languages in the QHP's service area

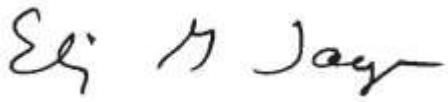
indicating the availability of free language assistance services through a QHP issuer's call center.

We also recommend that CMS specifically require taglines on issuer's websites. As we recommended in our comments to last year's Draft Letter to Issuers, QHP issuer Websites that contain consumer-facing 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.

Conclusion

Thank you for the opportunity to provide our feedback. If you have any questions or need any further information, please contact Mara Youdelman, managing attorney of our DC office (Youdelman@healthlaw.org, 202-289-7661).

Sincerely,



Elizabeth G. Taylor
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