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February 21, 2014

Centers for Medicare and Medicaid Services
Center for Consumer Information and Insurance Oversight
By Email: FFEcomments@cms.hhs.gov

RE: 2015 Draft Letter to Issuers in the Federally-Facilitated Marketplaces

To Whom It May Concern:

Bi-State Primary Care Association is pleased to respond to the above-referenced draft Letter to Issuers, published by the Center for Consumer Information and Insurance Oversight (CCIIO) within the Centers for Medicare and Medicaid Services (CMS) on February 4, 2014 (“Draft Letter”). Bi-State has worked in collaboration with the National Association of Community Health Centers, and uses its letter and comments as a template for our responses.

Established in 1986, Bi-State is a nonpartisan, nonprofit 501(c)(3) charitable organization that promotes access to effective and affordable primary care and preventive services for all, with special emphasis on underserved populations in New Hampshire and Vermont. Bi-State works with federal, state and regional health policy organizations, foundations and payers to develop strategies, policies and programs that provide and support community-based primary health care services in medically underserved areas. Our members include Community Health Centers, which is inclusive of Federally Qualified Health Centers (FQHCs), Rural Health Clinics, private and hospital-supported primary care practices; Community Action Programs, Health Care for the Homeless programs, Area Health Education Centers, Clinics for the Uninsured and social service agencies. Our members care for approximately 320,000 patients in Vermont and New Hampshire.

I. Overview of Comments

The Draft Letter describes the standards CMS will use to certify health plans as meeting the criteria set forth in the Affordable Care Act (ACA) and its implementing regulations to offer a qualified health plan (QHP) on a federally-facilitated Marketplace (FFM) in 2015. The area where the Draft Letter **departs most significantly from the comparable guidance for 2014 relates to the inclusion of “essential community providers” (ECPs) in QHP networks.**

As Health Centers are key ECPs, Bi-State’s comments focus on ECP contracting requirements and on network adequacy in QHP coverage in general. Bi-State applauds CMS for its work to improve QHP requirements in this area in 2015.

Rigorous implementation of the ACA provisions on ECPs, and more specifically its protections for FQHCs, is critical in order for the Marketplaces to offer adequate coverage in medically underserved areas. Effective primary care is the linchpin of many of the ACA’s reforms, and FQHCs are the chief single source of primary care for low-income individuals who now have access to affordable health insurance coverage for the first time as a result of the ACA.

In our comments on the 2014 draft Letter to Issuers, **we have serious concerns that the standards requiring QHPs to contract with ECPs were insufficient.** CMS’s processes for certifying QHPs in plan year 2014 relied too heavily on state licensure and health plan accreditation processes to determine network adequacy. As to ECPs, CMS proposed to certify QHPs that could demonstrate having met a “safe harbor” of demonstrating that at least twenty percent (20%) of ECPs in the service area participated in the plan’s provider networks, and that

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the plan had offered coverage to at least one ECP in each ECP category in the service area. In addition, issuers could include even fewer ECPs in their networks (10%) if they provided a narrative justification.

CMS finalized the 2014 Letter to Issuers substantially as proposed. As a result, in our opinion, the concerns expressed by Bi-State and other advocates for patients and safety net providers are being borne out in the 2014 plan year. ECPs are not adequately represented in plans' networks, and in particular, low-income QHP enrollees in medically underserved areas do not have enough available sources of primary care.

Bi-State applauds the fact that through the 2015 Draft Letter, CMS has recognized that more rigorous network adequacy and ECP network requirements are necessary for the 2015 plan year, however we urge CMS to do more. The improvements in the draft issuance are only incremental. Qualitative rather than incremental changes in approach are needed.

For example, we believe CMS's approach of **deeming the ECP network requirements to be met provided that the QHP contracts with a fixed percentage of ECPs in the service area is inherently arbitrary.** CMS proposes to raise this fixed percentage standard from twenty to thirty percent (20 to 30%) for the year 2015, when in fact, this approach to network adequacy is not sound. To ensure "reasonable and timely access" to ECPs, as stated in the regulation, **CMS's standards for ECPs should take into account the demographics, geographical features, transportation structure, and number and types of ECPs in each plan's service area, among other issues – not simply the percentage of ECPs with which the plan has contracted.**

We are, therefore, particularly concerned by the suggestion that the U.S. Department of Health and Human Services (HHS) intends to amend 45 C.F.R. § 156.235 to formalize the thirty-percent (30%) standard in regulation. As CMS's experience between 2014 and 2015 has shown, it is impossible to establish a fixed percentage of ECPs within a service area that can ensure sufficient ECP access for all plan enrollees.

Bi-State appreciates the fact that CMS addressed the issue of FQHC payment on the Marketplaces in the Draft Letter. The applicable payment rate is closely related to network adequacy. Without payment protections, as HHS has acknowledged, QHP issuers could discriminate against ECPs by offering contracts with rates so unfavorable that the ECP cannot feasibly accept the contract.

One reason that Congress designated ECPs as "essential" is that they serve as the safety net care system for uninsured populations in underserved areas. The ACA does not fundamentally change that; the ACA coverage expansions do not relieve the problem of the uninsured. It is, therefore, **critical that ECPs be reimbursed adequately by payers (especially such large-volume payers as the Marketplace plans) so that the funding they receive specifically to care for the uninsured is properly directed to that purpose.**

FQHCs are unique among ECPs in that the ACA requires a specific payment rate (the Medicaid prospective payment system (PPS) rate) for covered items or services provided to a QHP enrollee by an FQHC. Bi-State applauds CMS for recognizing in the Draft Letter that FQHCs are entitled to receive the Medicaid PPS rate for services provided out-of-network. We urge CMS, in the final Letter to Issuers, to clarify and strengthen its statements on this point. **In particular, we urge CMS to clarify first, that QHPs must cover and pay non-contract FQHCs for any service of a type covered by the QHP; and second, that the applicable rate of payment is determined by the Medicaid PPS methodology, as described at Section 1902(bb) of the Social Security Act.**

Bi-State strongly supports the proposal that HHS amend 45 C.F.R. § 156.235, the regulation dealing with ECP network inclusion and FQHC payment. We agree that the regulatory provision needs to be clarified and strengthened. As described more below, we believe that HHS has misinterpreted the ECP contracting provision and the FQHC payment provision and urge HHS to use amended regulations as the opportunity to bring those provisions into alignment with the statute.

II. Background on Health Centers and Affordable Insurance Marketplaces

Nationally there are almost 1,300 Health Centers with more than 9,300 sites serving more than 22 million patients nationwide. In Vermont and New Hampshire, there are 22 FQHC. Our FQHCs receive a federal grant under Section 330 of the Public Health Service Act (“PHS Act”), 42 U.S.C. § 254b, from the Bureau of Primary Health Care (“BPHC”), within the Health Resources and Services Administration (HRSA). Under this authority, Health Centers fall into four general categories: 1) those Health Centers serving medically underserved areas; 2) those serving homeless populations within a particular community or geographic area; 3) those serving migrant or seasonal farmworker populations within similar community or geographic areas; and 4) those serving residents of public housing.

To qualify as a Section 330 grantee, a Health Center must be serving a designated medically underserved area or a medically underserved population. In addition, a Health Center’s board of directors must be made up of at least fifty-one percent (51%) users of the Health Center, and the Health Center must offer services to all persons in its area, regardless of one’s ability to pay. BPHC’s grants are intended to provide funds to assist Health Centers in covering the otherwise uncompensated costs of providing comprehensive preventive and primary care and enabling services (such as translation, transportation services, smoking cessation classes, etc.) to uninsured and underinsured indigent patients, as well as to maintain the Health Center’s infrastructure. Patients from eligible communities, who are not indigent and are able to pay or who have insurance, whether public or private, are expected to pay for the services rendered. Approximately 41% of Health Center patients are Medicaid or Children’s Health Insurance Program (CHIP) recipients, approximately 8% are Medicare beneficiaries, and approximately 36% are uninsured.

Effective implementation of coverage under the Marketplaces is important to Health Centers, just as Health Center participation is critical to the success of the Marketplaces. Health Centers provide cost-effective and cost-efficient primary and preventive health care to a predominantly low-income population, and they embody principles of patient-centered primary care that Congress sought to propagate through various provisions of the ACA.

In the ACA, Congress specifically recognized the critical role of Health Centers and other safety-net providers in Marketplace QHP networks. Specifically, Patient Protection and Affordable Care Act (PPACA) § 1311(c)(1) provides that the Secretary

shall require that to be certified [to operate on the Marketplace] a [qualified health] plan shall, at a minimum . . . include within health insurance plan networks those essential community providers, where available, that serve predominately low-income, medically-underserved individuals, such as health care providers defined in section 340B(a)(4) of the Public Health Service Act. . . .

FQHCs are listed as covered entities under Section 340B of the Public Health Service Act and, hence, are a category of ECPs.

In PPACA, Congress also specifically acknowledged the critical role of FQHCs in providing coverage on the Marketplaces, by requiring adequate payment by QHPs for services rendered by FQHCs:

If any item or service covered by a qualified health plan is provided by a Federally-qualified Health Center (as defined in section 1905(l)(2)(B) of the Social Security Act . . . to an enrollee of the plan, the offeror of the plan shall pay to the center for the item or service an amount that is not less than the amount of payment that would have been paid to the center under Section 1902(bb) of such Act . . . for such item or service.

PPACA § 1302(g)). Section 1902(bb) of the Social Security Act, in turn, contains the requirement that states pay FQHCs furnishing Medicaid services according to a cost-related PPS methodology.

III. Comments

Bi-State's comments focus on the network adequacy requirements and the ECP contracting requirements in the Draft Letter in Chapter 2, Sections 3 and 4.

A. Network Adequacy (Chapter 2, Section 3)

Bi-State commends CMS for acknowledging in this section of the Draft Letter that greater CMS oversight and more ambitious provider network requirements are needed for the QHPs operating on the FFMs. **Advocates for consumers and health care providers are concerned by QHPs' extensive use of narrow provider networks in plan year 2014. In order for members to have meaningful access to the set of essential health benefits described in the law (and any additional services offered by the QHP issuer), more robust insurer networks must be required.**

By way of example, in New Hampshire, we have only one QHP. They have for the first time created a narrow network thereby eliminating many hospitals in our FQHC service areas. This limits the FQHCs ability to provide the full continuum of services through the FQHC medical home model. At some of our FQHCs, their patients must be referred to other providers in the area because the hospital in which the FQHC has a relationship with is out of network and not included in the hospital narrow network.

While Bi-State appreciates the more proactive approach to QHP networks reflected in the 2015 Draft Letter, as contrasted with the 2014 version, we do not feel the Draft Letter goes far enough.

We fully support the network adequacy changes CMS has proposed for 2015 on a procedural level. In 2014, CMS essentially delegated the evaluation of provider networks to states (where state law required an assessment of network adequacy as part of the licensure process) and accreditation entities.

Network adequacy is too critical an aspect of QHP coverage for CMS, as the regulating agency, not to play an active role. We support CMS's proposal for plan year 2015 to require issuers to submit a provider list including all in-network providers and facilities for all plans, which CMS will review. We also support CMS's proposal to focus most closely on types of providers that have historically been in shortage in specific areas, including primary care providers.

However, more detail is needed in the Draft Letter to make the evaluation meaningful. **We recommend that CMS establish specific "reasonable access" standards and provide a template for QHPs to complete.** We encourage CMS to borrow from the standards used in Medicaid managed care, where Medicaid managed care organizations are required to demonstrate that they offer an "appropriate range of preventive, primary care, and specialty services that is adequate for the anticipated number of enrollees in the service area," and maintain "a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area." 42 C.F.R. § 438.207(b). Specifically, **CMS should establish the following:**

- **minimum provider-enrollee ratios;**
- **minimum provider-enrollee ratios by specialty;**
- **geographic accessibility standards (maximum driving time / distance);**
- **promoting the delivery of services in a culturally competent manner to all enrollees, including those with limited English proficiency; and**
- **making services accessible to the disabled.**

See 42 C.F.R. §§ 438.206(c)(1), 438.207(b).

Given the centrality of primary care providers in Marketplace coverage and the acknowledged scarcity of primary care providers in QHP networks, CMS should establish minimum network requirements for

primary care providers in general and for FQHCs in particular. As noted below, we believe the ACA requires that QHPs contract with any willing Health Center. But if CMS persists in interpreting the statutory ECP contracting requirement (PPACA § 1311(c)(1)(C)) as a network adequacy requirement, we have provided below specific network adequacy recommendations regarding FQHCs. (Please see Section III.B.)

In addition, similar to the framework under Medicaid managed care (*see* 42 C.F.R. § 438.206(b)(4)), **we recommend that CMS's network adequacy review include a determination of whether the issuers' plans offer out-of-network coverage under the conditions required by the ACA.** For example, as we discuss in more detail below, Marketplace plans are required to pay for out-of-network emergency services and services provided by FQHCs, and, therefore, the plans' network submissions to CMS should describe their policies on such services.¹

Finally, as noted in our comments on the 2014 Letter to Issuers, Bi-State feels that provider contracts offered on legally compliant terms are key to network adequacy. As discussed in more detail below, we recommend that CMS require plans to submit model provider agreements for each type of provider as part of the network adequacy determination.

B. ECP Network Requirements (Chapter 2, Section 4)

Bi-State appreciates the fact that through this issuance, CMS has made clear its goal of improving access to ECPs in 2015. In addition, **we believe that CMS and Bi-State are in agreement on two basic principles: 1) that access to ECPs should be meaningfully available to plan enrollees in all service areas; and 2) that provider contracts for ECPs should be offered in good faith and on legally compliant terms. On the specifics of each principle, however, we have some disagreement.**

Bi-State's concern is that the Draft Letter for 2015 makes only incremental changes from the prior issuance, while hewing to the same basic policies as last year. In order to meaningfully improve the plan networks for 2015, CMS should revise its strategies more fundamentally, as we describe below.

1. HHS should amend the regulation to require plans to contract with any willing ECP.

The ACA requires plans to contract with "essential community providers," "where available," that provide critical services in underserved areas. PPACA § 1311(c)(1)(C). In implementing regulations finalized in March 2012, HHS interpreted this as a network adequacy requirement, which could be satisfied by contracting with a subset of ECPs. Specifically, as a condition of certification, QHP networks must include "a *sufficient number* and geographic distribution of essential community providers, where available, to ensure reasonable and timely access to a broad range of such providers for low-income, medically underserved individuals in the QHP's service area, in accordance with the Marketplace's network adequacy standards." 45 C.F.R. § 156.235(a)(1) (emphasis added).

We support the proposal in the Draft Letter to amend and clarify the regulation. **However, rather than amending the regulation to formalize the fixed percentage standard (30% of available ECPs in the service area) proposed by CMS, we recommend that the regulation be amended to specify that QHPs *must contract with any willing ECP* on terms that are legally compliant with respect to payment rate.**

¹ We are aware that issuers were required to submit "access plans" for the 2014 (addressing, among other issues, access to out-of-network services) only for non-HMO products, so long as their state was determined by HHS to have adequate network adequacy review for HMO products. We recommend that CMS revise its policies on that point this year. CMS should review network adequacy (including out-of-network access) for all types of plans.

We believe HHS’s network adequacy approach was incorrect as a matter of both statutory construction and sound public policy. In PPACA § 1311(c), Congress premised the requirement to contract with ECPs on one condition: that the ECP be “available.” In the implementing regulation, HHS interpreted that provision as authorizing a plan to contract with only a “subset” of ECPs. *See* 76 Fed. Reg. at 41,899. HHS’s justifications for this interpretation in the preambles to the proposed and final rules appeared to be grounded more in policy than in the statutory language: HHS felt that such a policy would encourage “network flexibility for issuers.” 77 Fed. Reg. at 18,421.

Bi-State believes that Congress did not intend to authorize plans to avoid contracting with an ECP (let alone 70% or 80% of ECPs in the service area – the proportion of ECPs whose exclusion is justified under the fixed percentage standards in the 2014 and 2015 Letters to Issuers, respectively) on the ground that the ECP is “unavailable” because it does not fall within the subset with which the plan chose to contract. Such a reading is circular and renders nugatory the statutory requirement at PPACA § 1311(c)(1).

Moreover, the structure of the statute indicates that Congress did not view the requirement that QHPs contract with ECPs as a network adequacy requirement. PPACA § 1311(c) sets forth the responsibilities of the Secretary in setting certification requirements for QHPs. That subsection contains a paragraph addressing network adequacy (PPACA § 1311(c)(1)(B)) and a separate paragraph addressing the inclusion of ECPs in provider networks (PPACA § 1311(c)(1)(C)) – thus, indicating that the latter is a true contracting requirement, not merely a component of the network adequacy determination. In addition, the statutory label “essential” clearly conveys that plans should *not* have discretion to exclude from the network an ECP willing to accept a contract.

In short, it was an unauthorized interpretation of the statute for HHS to promulgate a regulation authorizing QHPs to contract with only a subset of ECPs, and we urge HHS to correct the regulation through amendments.

2. In the alternative, HHS should at minimum amend the regulation to require QHPs to contract with any willing FQHC.

FQHCs are of particularly crucial importance as QHP network providers, because they are the largest single source of primary care in medically underserved areas. Primary care is the linchpin of the “triple aim” reflected in the ACA: driving down prices, improving the quality of care, and improving patients’ experience.

FQHCs that receive Section 330 funds, by definition, have been designated to serve a medically underserved area or an underserved population (homeless, migrant, or residents of public housing) within an area. This designation alone shows that BPHC has determined the FQHC to be an essential source of care in that location or for that group and that the regulatory requirement of “reasonable and timely access” to primary care providers would not be met without the FQHC’s participation.

QHP issuers can achieve network adequacy goals in underserved areas only if their plans include FQHCs. If HHS refuses to consider a regulatory “any willing provider” requirement for *all* ECPs, then we recommend that HHS (both through rulemaking and through the Letter to Issuers) require QHPs to offer any willing FQHC a legally compliant contract, and for the remainder of ECPs, retain the network adequacy standard.

3. CMS should omit the use of a fixed percentage standard for ECP contracting in the Letter to Issuers, and HHS should not add such a fixed percentage standard to the regulation.

If HHS decides to retain the “network adequacy” framework for ECP contracting in its regulations, then Bi-State urges CMS, in its final Letter to Issuers, to publish standards that meaningfully determine whether in each service area, members have “reasonable and timely access to a broad range” of ECPs. The standards in the Draft Letter do not serve that purpose.

Bi-State objects particularly to the use of a fixed percentage standard that serves as a proxy for the determination of whether a QHP has actually met the requirement of having a “sufficient number and geographic distribution of essential community providers.”² As we discuss in more detail below, the requirement to contract with a certain percentage of ECPs (even in combination with the “one per type per county” requirement) is too blunt an instrument and does not measure whether meaningful access to ECPs is met as contemplated in the regulations. Such a standard is inherently arbitrary.

Moreover, the use of the thirty percent (30%) requirement effectively *invites* plans to exclude from their networks a portion—in fact, a sizable majority—of providers deemed “essential” by Congress. We do not believe that type of policy fulfills either the statutory or the regulatory intent. If CMS insisted on using a standard that serves as a proxy for a meaningful determination of ECP network adequacy (effectively, a safe harbor), the only appropriate one would be where a plan had included in its network *every available ECP*, but nonetheless, plan members did not have adequate access due to shortages.

The added requirement in the Draft Letter that the issuer show it has offered a contract to “at least one ECP in each ECP category in each county” in the service area does not make the thirty percent (30%) standard any more acceptable. The standard does not take population, demographics, or geographical features of a service area into account. For example, highly populous counties with a large number of medically underserved residents—for example, Los Angeles County, California (population 10 million) and Cook County, Illinois (population 5.2 million)—would not be adequately served by one Health Center participating in a health plan. Similarly, in a geographically large, rural county, a Health Center located in one corner of the county would not be accessible in a “timely” fashion to plan enrollees who live on the other side of the county.

Instead, every QHP should be required to make the full showing of network adequacy described on page 21 of the Draft Letter; i.e., to show that the “provider network(s), as currently designed, provides an adequate level of service for low-income and medically underserved enrollees.” No proxy standard should be used.

In light of these concerns, Bi-State is particularly concerned at the suggestion in the Draft Letter that HHS intends to add the thirty percent (30%) standard to the regulation, 45 C.F.R. § 156.235. If it is inappropriate to include that standard in CMS’s certification criteria for QHPs on the FFMs, as we argue above, then it is certainly inappropriate to formalize it in regulation. We strongly discourage HHS from pursuing that approach.

4. Failing amendments to the regulations embracing an “any willing provider” approach for ECPs, CMS should apply a more rigorous network adequacy standard in the Letter to Issuers.

² While the Draft Letter does not use this term, the thirty percent (30%) standard is effectively a safe harbor. A safe harbor is generally defined as a regulation that “reduces or eliminates liability under the law for excusable violations, provided the person or organization acted in good faith.” See M. Susan Ridgely, Michael D. Greenberg, *Too Many Alerts, Too Much Liability*, 5 St. Louis U. J. Health & Pol’y 257, 291 (2012). The thirty percent (30%) standard effectively excuses a QHP from having to satisfy the ECP contracting requirement in the regulations. The safe harbors most familiar in health care are those promulgated by HHS to protect health care organizations from liability for violations of the Anti-Kickback Statute. See 42 C.F.R. § 1001.952. The Anti-Kickback Statute protects against fraud on health care programs, and the safe harbors set forth types of actions that are excusable because they do not involve fraudulent intent.

The requirement to include a “sufficient number” of ECPs in plan networks, by contrast, is highly fact-intensive. The requirement does not involve intent, but instead refers only to outcome. The concept of “excusable” violations, on which safe harbors are typically premised, therefore, does not apply here. There is no proxy rule that can stand in for a viable determination of ECP network adequacy. For example, if a health plan excluded 80% of ECPs in the service area, and that caused ECPs not to be reasonably accessible to plan enrollees, then the purpose of the ECP network adequacy rule would be undermined.

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45 C.F.R. § 156.235(a) requires that the QHP issuer: 1) have a sufficient number *and geographic distribution* of ECPs in its network; 2) to ensure reasonable *and timely* access; 3) to a *broad range* of such providers for low-income, medically underserved individuals in the service area. The fixed percentage standard that CMS proposed in the Draft Letter does not address the three considerations indicated in italics above: geographic distribution of ECPs, population and demographic features of the service area and adequate representation of various types of ECP.

As noted above, we strongly believe that only an “any willing provider” standard for all ECPs fulfills Congress’ intent. In the event, however, that HHS maintains its present regulatory approach, we recommend that CMS apply numerous standards for all ECPs, including the following. (The Medicaid managed care delivery network requirements, at 42 C.F.R. §§ 438.206 and 438.207, could inform the development of these standards.)

First, CMS should require that QHPs include any willing FQHC in their networks. Because effective primary care is central to the reforms contained in the ACA, FQHCs (medical home to millions of individuals who are eligible to seek coverage through the Marketplaces) are uniquely important as ECPs. In addition, as noted above, Health Centers by definition serve medically underserved areas or populations. The ECP standards applied on the FFMs should reflect the unique role of FQHCs.

Bi-State also recommends that CMS provide a model QHP contract addendum for use with FQHCs. This addendum could be organized similarly to the model contract addendum for Indian health providers included as an attachment to the Draft Letter. (The Draft Letter also requires QHPs to contract with all available Indian health providers, similar to the “any willing provider” standard for FQHCs that we propose here.) It is appropriate that FQHCs and Indian health providers be treated similarly in both respects. Like Indian health providers, unique payment and other protections apply to Health Centers. Bi-State recommends that CMS work with the National Association of Community Health Centers to develop a model contract addendum.

Second, as part of its overall network adequacy evaluation, CMS should impose provider-to-enrollee ratios and proximity requirements. Both the ratio and the proximity requirement would be individualized for each ECP type to take into account the importance of that type of provider to the network and the expected volume of service usage.

As noted above, we believe CMS should require QHPs to contract with any willing FQHC, but if CMS does not accept that suggestion, we recommend that the ratio and proximity requirements for FQHCs would be more rigorous than for other ECPs. As an example, CMS might require that for FQHCs, the issuer contract with FQHCs in sufficient volume to ensure that the ratio of enrollees to individual FQHC providers (physicians, physician assistants and nurse practitioners) is at least 1:1,200. With respect to geography, CMS could require that the issuer’s network include an FQHC within 10 miles or 15 minute’ driving distance from each enrollee’s residence.

Bi-State is particularly concerned about the representation of rural FQHCs in QHP networks. It has been brought to our attention that FQHCs have been excluded from QHP networks even in remote service areas where the FQHC is the only available primary care provider. Failure to recognize the importance of including these providers will result in decreased appointment availability, excessive travel time and increased wait times for individuals who rely on the FQHC as their only available resource for primary care services.

Third, CMS should examine other access to care issues, including opening hours, cultural competency, and disabled accessibility. “Reasonable and timely access” to ECPs will be achieved only if the enrollee has access to care that is delivered with sensitivity to the patient’s needs. In evaluating ECP network adequacy, CMS should consider whether the network includes ECPs that have extended weekday (evening) hours and are available on weekends as well. In addition, CMS should evaluate whether the QHP has contracted with ECPs in the service area that provide culturally competent services, particularly for non-English speakers. Finally, accessibility of ECPs to the disabled should be considered.

Fourth, the evaluation should consider whether the QHP has contracted with each ECP to perform the full range of services covered by the QHP. HHS noted in the preamble to its final rule on QHP certification that although the ACA does not require plans to cover any specific procedure provided by an ECP, HHS “generally anticipate[s] and expect[s] QHP issuers will contract with essential community providers for all services furnished by the provider that are otherwise covered by the QHP.” 77 Fed. Reg. at 18,421.

Bi-State is concerned that this expectation is not being fulfilled in the 2014 plan year. We have learned of cases where QHPs contract with FQHCs for a very limited set of services (for example, only immunizations). One key (and unique among ECPs) benefit that an FQHC offers as an ECP is the continuum of primary care and enabling services that it provides to patients. Those benefits are lost when the QHP contracts for such a narrow scope of services. “Reasonable and timely access” to ECPs means that plan enrollees have access to the key services provided by that type of ECP.

Finally, after applying all other network requirements, CMS could also require that plans contract with at least a certain percentage of ECPs a higher percentage standard, applicable to all ECPs. We propose that CMS require an issuer to include in its network at least 70% of all ECPs in the service area.

We emphasize that the five types of requirements described above should be cumulative, not exclusive. For example, in many cases, a QHP issuer would be required to contract with more than 70% of ECPs in order to meet the prior three sets of requirements.

5. CMS should clarify the procedural requirements for QHPs to contract with ECPs.

Whatever type of requirement that CMS proposes for ECP contracting, CMS should clarify *how that requirement works procedurally*, so that plans will understand their obligations. The standards used in the Draft Letter, while they represent an improvement over the 2014 Letter to Issuers, are still confusing.

- With respect to the “30% standard,” the Draft Letter states that an issuer must demonstrate that that percentage of the ECPs “participate in the issuer’s network.” Issuers could interpret this as meaning that the standard is met if an ECP currently participates in a different product (for example, a Medicaid managed care plan) that the issuer offers. It is not reasonable to assume based on the ECP’s participation in the Medicaid plan that the ECP will participate in the issuer’s Marketplace plan in 2015, as the Medicaid plan may offer more acceptable terms, or the ECP may have little remaining capacity to take on new patients.
- The Draft Letter states (with respect to the “one per type per county” rule) that “the issuer [must] *offer[] contracts in good faith prior to the benefit year*” to certain ECPs. This wording represents an improvement over the 2014 Letter to Issuers, in that CMS has clarified that a contract offer is only in “good faith” if it includes terms that “a willing, similarly-situated, non-ECP provider would accept or has accepted.” But this standard, too, is inadequate in that it does not recognize that unique legal requirements apply to some types of ECPs, including Health Centers. For FQHCs, we maintain that the only “good faith” contract is one that offers payment based on the legally-required Medicaid PPS rate.

Instead of the two standards above, we recommend that in each case, the issuer be required to show that it has offered to the provider a good faith and legally compliant contract to the ECP to participate in 2015 in the network of the Marketplace QHP for which certification is sought.³

³ Bi-State also recommends that CMS require all contractual offers to be sent to providers via certified mail for the purpose of acknowledging receipt and should be sent 90-180 days in advance of submission of the proposed offer list. This establishes that ECP recruitment was underway well in advance of submission deadlines. Additionally, inclusion on an issuer offer list in no way indicates that the contract was legally compliant or deemed acceptable by the provider. Those ECPs in receipt of proposed contractual agreements should be surveyed for the purpose of determining the QHP level of engagement during the contract negotiation and execution process. FQHCs have reported that in some instances, negotiations can take up to a year to complete.

In addition, as noted above in our comments on network adequacy, we recommend that CMS require issuers to provide for CMS's review model provider agreements for each ECP type in order for CMS to evaluate whether the contract terms are reasonable and legally compliant. CMS should *not* accept as evidence of an ECP's participation in an issuer's plan the issuer's representation that the ECP presently participates in other products offered by the issuer, or the issuer's representation that the issuer merely has offered or will offer the ECP a contract (without any evidence of contract terms).

We want to emphasize that for ECPs, the terms of proposed provider contracts are as important as the mere offering of contracts in determining whether it is feasible to participate in QHPs' networks. This is why it is particularly important that CMS require, as a condition of certifying a QHP on a federally-facilitated Marketplace, that issuers present model agreements with each type of ECP for CMS's review. Such review would be similar to the type of review that CMS undertakes when it determines, under Medicaid, whether a state's contract with a managed care organization will ensure sufficient provider network participation to meet statutory and regulatory requirements. PPACA's provisions on Marketplaces, like the Medicaid statute, impose specific rules for contracting with categories of providers. CMS will have no means of determining whether those requirements are met unless, as administrator of the FFM, CMS engages in a more searching review of potential contracts with providers than is indicated in CMS's Draft Letter.

For the same reason, as noted above, we believe CMS should work with the National Association of Community Health Centers to develop a Model Contract Addendum for FQHCs. The FQHC Model Contract Addendum should specify that QHPs are required to reimburse FQHCs according to the Medicaid PPS payment methodology. For FQHCs, a "good faith" offer of a contract can only be defined as one that honors the PPS payment guarantee contained at PPACA § 1302(g) and other unique legal requirements and protections that apply to Health Centers. Many times, in effort to contract with large numbers of providers on a compressed timeframe, insurers conduct mass contract mailings. A generic template used for all types of providers is insufficient; instead, each contract offered must comply with any legal obligations that apply to the type of ECP at issue.

Finally, we wish to emphasize the importance of transparency and access to information on QHP networks. CMS should make available to the provider community the network adequacy information that it receives from QHPs. Increased emphasis on transparency by CMS is of critical importance in the administration of the FFMs, and we hope that states administering their own Exchanges will follow that transparency by example. Many of the FQHCs that have been excluded from QHP networks have asked to obtain the information that QHP issuers submitted to CMS and to state licensing and regulatory authorities for the purpose of demonstrating network adequacy. Health Centers and statewide primary care associations have been unable to gain access to this information and, therefore, have no way to either validate or dispute the accuracy of the information submitted by QHP issuers. At present, the FQHC community has little confidence in the network adequacy review process even in the presence of regulations that clearly establish guidelines for the inclusion of ECPs in provider networks.

In the same vein, we note that the list of ECPs included as an addendum to the Draft Letter appears to be missing significant numbers of ECPs (clearly identifiable because of they are "covered entities" under the 340B program), including a significant number of FQHCs. While we hope that CMS will withdraw its use of a fixed percentage standard that serves as a proxy for demonstrating ECP network adequacy, we note that the use of that fixed percentage standard makes it particularly important for CMS to rely on a full list of ECPs, to that the full number will be considered in deriving minimum contracting numbers based on percentages. We support CMS's proposal to allow QHPs to "write in" ECPs omitted from the list.

- 6. As part of its ECP network review, CMS should ensure that QHP payment to FQHCs complies with federal law.**
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Bi-State commends CMS for addressing in the Draft Letter the legal requirements for payment to FQHCs in its Draft Letter to Issuers, and for reaffirming the QHPs' out-of-network payment obligations for FQHC services.

As CMS's discussion on page 27 of the Draft Letter implies, adequate payment to FQHCs is key to network adequacy. As HHS itself conveyed in the preamble to its March 27, 2012 final rule, plans should not be able to discriminate against ECPs by offering them rates that are so low that the provider is unable to accept them. 77 Fed. Reg. at 18,422.

Obtaining adequate payment is particularly important for Health Centers, because Section 330 of the PHS Act requires that a Health Center grantee "[make] and will continue to make every reasonable effort to collect appropriate reimbursement for its costs in providing health services to persons who are entitled . . . to medical assistance under . . . [a] private health insurance program. . . without the application of any discount." 42 U.S.C. § 254b(k)(3)(F). The reason that Congress, in Section 330 of the PHS Act, required Health Centers to seek sufficient payment from all payers was to ensure that Section 330 grant funds, dedicated to covering the costs of serving uninsured and underinsured individuals, would not be diverted to subsidize the costs of serving patients with full insurance coverage. If QHPs do not contract with FQHCs for reimbursement that supports the cost of providing services, then federal grant dollars are effectively being used to subsidize private insurance companies. This goes against the structure and purpose of the PHS Act.

Congress recognized this reality in PPACA § 1302(g), which requires QHPs to pay Health Centers according to the Medicaid PPS methodology for "any item or service covered by a qualified health plan [that] is provided by a Federally-qualified Health Center." PPACA § 1302(g) (as amended by PPACA § 10104(b)(2)). The Medicaid PPS methodology is a cost-related reimbursement system, and the use of that system in the Marketplace context helps ensure that QHP payment to Health Centers will support the cost of services provided.

- a. **HHS should amend its regulations to clarify that QHPs must reimburse Health Centers, without exception, according to the Medicaid PPS requirements.**

The implementing regulation, at 45 C.F.R. § 156.235(e), strays from the statutory payment mandate by stating that QHP issuers and FQHCs may

mutually agree[] upon payment rates other than those that would have been paid to the center under the [Medicaid PPS methodology], as long as such mutually agreed upon rates are at least equal to the generally applicable payment rates of the issuer. . . .

Since CMS indicated in the Draft Letter that HHS may amend the regulation, Bi-State is taking the opportunity in these comments to recommend that HHS amend the regulation *to delete the second sentence in § 156.235(e)*, which contains the above-quoted provision.

HHS justified its decision to authorize plans to contract with Health Centers for lower rates by citing PPACA § 1311(c)(2), which states, with respect to ECPs in general, that "[n]othing in [the ECP contracting provision] shall be construed to require a qualified health plan to contract with a provider described in such paragraph if such provider refuses to accept the generally applicable payment rates of such plan." HHS explained in preambles to the regulations that it considered PPACA §§ 1302(g) and 1311(c)(2) to be "in conflict."⁴ 76 Fed. Reg. at 41,899. HHS expressed concern that if § 1302(g) were enforced as written, then health plans may not contract

⁴ We do not believe there is an irreconcilable conflict between these provisions. As a principle of statutory construction, "[s]pecific terms prevail over the general in the same or another statute which otherwise might be controlling." *Fourco Glass Co. v. Transmirra Products Corp.*, 353 U.S. 222, 229 (U.S. 1957). Therefore, the specific FQHC payment guarantee at PPACA § 1302(g) should take precedence over the reference to "generally applicable rates" for ECPs more broadly at PPACA § 1311(c)(2).

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with FQHCs. *Id.* In our opinion, however, that concern was ill-founded because Congress (through PPACA § 1311(c)(1)(C)) clearly expressed its intention that QHPs, as a condition of certification to offer coverage on the Marketplaces, be required to contract with all available ECPs (including FQHCs).

In effect, then, 45 C.F.R. § 156.235 contains two clear errors of statutory interpretation. HHS was forced into an incorrect interpretation of the FQHC payment requirement (PPACA § 1302(g)), reflected in subsection (e) of the regulation, in order to justify the incorrect interpretation of the ECP contracting requirement (PPACA § 1311(c)(1)(C)) reflected in subsection (a).

We encourage HHS, through regulatory amendments to 45 C.F.R. § 156.235(a) and (e), to correct these errors, and we encourage CMS to finalize a 2015 Letter to Issuers consistent with the correct interpretation of these statutory provisions.

b. CMS should clarify its statements concerning FQHC out-of-network services.

Bi-State applauds CMS for the inclusion of the section clarifying the FQHC payment protections specifically reaffirming that QHPs must cover out-of-network services provided by FQHCs and must reimburse FQHCs according to the Medicaid PPS methodology for those services. However, as noted above, Bi-State does not agree with HHS's conclusion that a payment methodology other than the Medicaid PPS methodology may be used in the contract (in-network) setting. We request that CMS strengthen its treatment of this topic and include several additional clarifications in its final Letter to Issuers.

In a June 8, 2012 letter to the National Association of Community Health Centers' Senior Vice President Daniel R. Hawkins, Jr., Timothy Hill, Deputy Director of the CCIIO, affirmed QHPs' obligation to cover out-of-network services provided by an FQHC. Mr. Hill's letter reasoned that a requirement for QHPs to reimburse FQHCs for out-of-network services at the FQHC's Medicaid PPS rate flows from the statutory payment requirement at PPACA § 1302(g). Mr. Hill's letter noted that pursuant to 45 C.F.R. § 156.235(e), QHPs and FQHCs could mutually agree upon lower rates in the contractual (in-network) setting, but that "if a QHP issuer does not have a contract with an FQHC," the Medicaid PPS rate would apply.

The Draft Letter to Issuers substantially reiterates these statements, with one qualification:

[S]tate law may define covered services for HMO plans to be limited to those services provided by in-network providers. In such cases, this requirement would not apply to non-emergent out-of-network services if provided by FQHCs.

Bi-State disagrees with this qualification. Specifically, we believe that PPACA § 1302(g) requires QHP issuers to reimburse Health Centers for out-of-network services regardless of the type of plan coverage offered through the QHP.

Bi-State requests that CMS clarify the following in the final Letter to Issuers:

1. A QHP must cover and pay a non-contracted FQHC for any service of a *type* (e.g., primary care evaluation and management visit, cholesterol screening) that is covered under the plan.
2. The QHP must reimburse the FQHC for such services according to the Medicaid PPS methodology described at Social Security Act § 1902(bb).
3. The cost sharing that a QHP may impose for FQHC out-of-network services may not exceed the cost sharing that would be imposed if the service had been provided in-network.
4. The exception for HMO plans stated in the Draft Letter should be reconsidered.

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As to the HMO exception, as noted above, we believe that PPACA § 1302(g) requires PPS payment for FQHC out-of-network services with no exception relating to plan type. We, therefore, believe CMS should in the Final Letter to Issuers omit this exception.

In addition, we are concerned that the exception is worded vaguely in the Draft Letter, and the lack of specificity will undermine the statutory guarantee of PPS payment. We understand that CMS may in fact have intended for this exception to apply only to closed-panel HMOs; *i.e.*, the types of HMOs described in 45 C.F.R. § 156.235(a)(2), which provide “a majority of covered professional services through physicians employed by the issuer or through a single contracted medical group.” We request that if CMS did in fact intend to apply the exception to that limited group, that CMS so specify in the final Letter to Issuers.

Bi-State also recommends that if CMS insists on keeping this exception in the final Letter to Issuers, CMS clarify the definition of “HMO plans” and also clarify the type of state statutory language that would trigger the exception. The definition of an HMO may vary from state to state. The Draft Letter to Issuers provides no guidance on how ECPs can determine whether the exception applies in their state. ECPs would need to research this requirement before engaging in contract negotiation for the 2015 enrollment year. Specifically, there are several variations of HMO products (POS, EPO, etc.) that providers would need to be able to identify in order to determine if the exception applied to those products. Because of its vague wording, this exception limits FQHCs’ ability to engage in contract negotiation activities with QHPs.

Further, if CMS retains the HMO exception, we request that CMS clarify that the exception does *not* exempt HMOs in general from the FQHC out-of-network payment requirement. QHP issuers cannot avoid the FQHC out-of-network coverage and PPS payment requirement simply by defining their benefit to be limited to in-network services.

We feel that these clarifications are consistent with the statute and necessary to give effect to the out-of-network coverage protections required by PPACA § 1302(g) and described in the Draft Letter.

* * * *

Thank you for the opportunity to comment on CMS/CCIIO’s Draft Letter to Issuers. While it is informal, this piece of guidance is very important to providers and plans. In addition, while it controls only CMS’s regulation of the federally-facilitated Marketplaces, many states look to CMS’s interpretations in their own Marketplace plan certification requirements and processes.

Bi-State appreciates the opportunity to provide input. Please do not hesitate to contact me by telephone at (603) 228-2830, extension 112 or by e-mail at tkuenning@bistatepca.org if you require any clarification on the comments presented above.

Sincerely,



Tess Stack Kuenning, CNS, MS, RN
President and Chief Executive Officer