

525 Clinton Street
Bow, NH 03304
Voice: 603-228-2830
Fax: 603-228-2464



61 Elm Street
Montpelier, VT 05602
Voice: 802-229-0002
Fax: 802-223-2336

www.bistatepca.org

July 27, 2015

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-2390-P
PO Box 8016
Baltimore, MD 21244-8016

Submitted via www.regulations.gov

RE: Proposed Rule for Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; 80 Fed. Reg. 31098 (June 1, 2015)

Dear Acting Administrator Slavitt:

Bi-State Primary Care Association appreciates the opportunity to comment on the proposed rule on above-referenced Notice of Proposed Rulemaking ("NPRM" or "Proposed Rule") published by the Centers for Medicare & Medicaid Services ("CMS") on June 1, 2015 (80 Fed. Reg. 31098).

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 Vermont and New Hampshire. 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 include Federally Qualified Health Centers (hereafter interchangeably referred to as health centers or 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.

In addition to caring for millions of Medicaid enrollees at any point in time, FQHCs also provide a stable, accessible medical home to individuals who churn between Medicaid, the Marketplace, and being uninsured. A fundamental characteristic of FQHCs is their commitment to serve all individuals, regardless of their insurance status or ability to pay. Over 70% of health center patients live below the poverty line; if these individuals are uninsured, they pay no more than a nominal fee to receive the full range of FQHC services. An additional 20% of FQHCs patients are between 100% and 200% of the poverty line; if uninsured, these patients are charged reduced fees based on a sliding scale. As a result, FQHCs provide consistent, affordable care for vulnerable individuals even as their insurance status and income fluctuate. For more information on FQHCs, please see Attachment 1.

Bi-State is focusing its comments primarily on issues that are of particular importance to health centers and the patients they serve. In addition to our comments, we fully endorse the National Association of Community Health Center's (NACHC) letter that will be submitted before the deadline. With NACHC's permission, our letter uses their template and parallels their comments and concerns.

Bi-State Primary Care Association Comments

RE: Proposed Rule for Medicaid and CHIP Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; 80 Fed. Reg. 31098 (June 1, 2015)

July 27, 2015

Page 2

SUMMARY OF KEY COMMENTS

In general, Bi-State applauds CMS for publishing a Proposed Rule that seeks to modernize Medicaid managed care by enhancing protections for beneficiaries, creating more uniformity of Medicaid rules with those governing the Marketplaces and Medicare Advantage (MA) plans, and introducing greater transparency in the standards used to establish and update capitation payments from states to managed care organizations (MCOs¹).

This section contains a summary of our most significant comments. In the following section, we discuss and explain each of these comments, and also include some additional comments.

§438.3(s)(3) - Interaction of 340B and Medicaid managed care

- Bi-State appreciates that CMS explicitly states that 340B providers are not legally responsible for protecting manufacturers from having to pay both a 340B discount and a Medicaid rebate on a managed care claim. In addition, we recommend that CMS:
- Add language to the preamble and regulatory text to:
 - Clarify that neither states nor MCOs may prohibit 340B providers who are in MCO networks from using 340B drugs for their patients;
 - Clarify that neither states nor MCOs may prohibit providers from using 340B drugs for their managed care patients as a condition of participating in an MCO's network;
 - Prohibit MCOs from paying lower rates for drugs purchased by 340B covered entities than for the same drugs when purchased by other MCO network providers. Similarly, states should be prohibited from requiring MCOs to pay lower rates for drugs purchased by 340B covered entities than for the same drugs when purchased by other MCO network providers; and
 - Prohibit MCOs from requiring 340B providers to use a methodology for identifying 340B claims that makes it highly difficult or impossible for these providers and their contract pharmacies to use 340B for Medicaid MCO patients.
- Permit 340B providers to report claims data directly to the state or the states' rebate contractor, bypassing the MCOs, such as is currently done in Oregon.
- Require MCOs to use separate BIN-PCNs for their Medicaid plans and to share the BIN-PCNs with 340B covered entities.
- Prohibit MCOs from using billing information from 340B Medicaid claims to reduce reimbursement for 340B commercial claims.

§438.4 – Appropriate costs for inclusion of actuarially sound capitation rates

- In the preamble discussion of which costs are appropriate to include when calculating actuarially sound capitation rates, CMS should clarify that the only FQHC-related costs that are appropriate for inclusion are those for payments made at the same rate as payments to similar providers.

§ 438.60 – Exceptions to prohibition on duplicate payments to MCO providers

- In the preamble discussion of permissible exceptions to the prohibition on duplicate payments to MCO network providers, CMS should state that:

¹ In these comments, we use the term MCOs to refer collectively to Managed Care Organizations, Pre-paid Inpatient Health Plans (PIHPs) and Pre-paid Ambulatory Health Plans (PAHPs.)

Bi-State Primary Care Association Comments

RE: Proposed Rule for Medicaid and CHIP Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; 80 Fed. Reg. 31098 (June 1, 2015)

July 27, 2015

Page 3

- As stated in the 2002 Rule, supplemental payments to FQHCs are one of the two types of payments to which this exception applies.
- States are legally responsible for ensuring that appropriate supplemental payments are made to FQHCs, and this legal responsibility may not be delegated to an MCO.

§438.6(c) – Value-based purchasing

- In recognition of the unique requirements faced by FQHCs, CMS should not permit states or MCOs to require FQHCs to accept risk for services beyond primary and preventive care as a condition of joining a MCO network. Specifically, CMS should:
 - Add language §438.6(c)(1) stating that the state may not require FQHCs to assume risk for services beyond primary and preventive care as a prerequisite for obtaining a managed care provider agreement.
 - Add a subparagraph (G) at the end of the list of conditions for CMS approval of MCO agreements in §438.6(c)(2)(i) stating: “Does not require FQHCs to assume risk for services beyond primary and preventive care as a prerequisite for obtaining a managed care provider agreement.”
- Clarify that states may impose additional requirements on MCO expenditures beyond those listed in this section if those requirements are statutorily mandated.
- Clarify in the preamble that an FQHC’s participation in risk-based or value-based purchasing arrangement has no impact on the supplemental payment obligation that the state owes directly to the health center.

§ 438.608(a)(8) Withholding payments in response to a “credible allegation of fraud”

- Require the state to notify the MCO of a pending investigation of a credible allegation of fraud.
- Require that these notifications be in writing, be certified by an appropriate state official, and contain enough detailed information for the provider to respond to the specific allegation.
- Require the state to recertify to the MCO and provider at regular intervals (e.g., every ten days) that the fraud investigation is ongoing.
- Require MCOs to process suspended payments to a provider on a timely basis once the allegation has been resolved in favor of the provider (e.g., within three days following notification from the state). Establish a maximum length of time for which the state and MCO can suspend payments prior to making a final determination as to the credible allegation of fraud.

§ 438.71(c)(2): Eligibility to serve as state-supported Choice Counselors

- Establish “one-stop shopping” for low-income persons to receive Choice Counseling (CC) by permitting organizations that receive federal and/or state support to provide similar services under the Marketplace to provide state-supported CC under Medicaid managed care, without being registered as enrollment brokers.
- For state-supported CC providers who are not enrollment brokers, ensure that appropriate conflict-of-interest protections are in place. Also, clarify that serving as a network provider for a health insurer does not constitute a conflict of interest provided that appropriate safeguards (such as those used in the Marketplace) are in place.
- If unwilling to modify the provisions as described above, at a minimum CMS should state in the preamble that states are permitted to contract with entities other than enrollment brokers to

Bi-State Primary Care Association Comments

RE: Proposed Rule for Medicaid and CHIP Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; 80 Fed. Reg. 31098 (June 1, 2015)

July 27, 2015

Page 4

perform the portions of “beneficiary support system” other than “choice counseling.” This would include assisting enrollees in understanding managed care. Also, CMS should clarify in the preamble that FFP for administrative costs is available for such a contract.

§ 438.214(b) and (e)– Credentialing process

- Clarify in the preamble on section § 438.214(b) that because FQHCs are already required by statute and HRSA policy to conduct credentialing for each licensed independent practitioner providing services on behalf of the health center:
 - States should permit and encourage MCOs to delegate credentialing of clinicians to FQHCs; and
 - Such delegation is not inconsistent with the requirement to establish a “uniform credentialing and recredentialing policy” under paragraph (b)(1) and does not run afoul of the nondiscrimination requirement.
- To offset financial incentives for MCOs to delay approving credentialing applications, CMS should:
 - Require MCOs to publicly report (e.g., on the state website) the average length of time they take the process credentialing applications, starting from the date that a complete application package is received.
 - Require MCOs to make payments to credentialed providers retroactive to the date that their completed credentialing application was received.

§438.68 – Network adequacy standards

- Significantly strengthen the requirements around network adequacy (NA) by establishing minimum NA standards for each of the provider types listed in §438.68(b) – e.g., primary care, OB/GYN. These standards should address, at a minimum:
 - Number and types of providers relative to the number of patients;
 - Language and physical accessibility;
 - Travel time and distance;
 - Wait times for appointments; and
 - Accessible hours for working populations.
- Give states the flexibility to establish different standards as long as:
 - The standards are at least as stringent as the CMS-established minimum standards; and
 - The state demonstrates that it has actively considered all factors outlined in §438.68(c).
- Require MCOs to contract with Essential Community Providers (ECPs) according to same standards applied to Qualified Health Plans participating in Federally-Facilitated Marketplaces. (i.e., contract with at least 30% of all ECPs in the service area, at least one from each category in each county, etc.)

COMMENTS

1. Alignment with Other Health Coverage Programs

1b. Appeals and Grievances – Bi-State supports CMS’ proposals to align appeal and grievance procedures among Medicaid MCO, Marketplace, and MA plans. Many of these proposals will increase beneficiary protections under Medicaid MCOs and will also reduce confusion among patients who

Bi-State Primary Care Association Comments

RE: Proposed Rule for Medicaid and CHIP Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; 80 Fed. Reg. 31098 (June 1, 2015)

July 27, 2015

Page 5

transition between these programs. Specific provisions that will be particularly beneficial to medically-underserved populations include:

- §438.408(b)(2) and (b)(3) - Shortening the time frames for MCOs to make decisions about standard and expedited appeals - §438.408(b)(2) and (b)(3).
- §438.408(d)(1) and (2) - Requiring the grievance and appeals notices be accessible for persons with disabilities and Limited English Proficiency.
- §438.424 - Requiring MCOs to authorize or provide the services in question within 72 hours of being informed of an Adverse Benefit Determination.

1c. Medical Loss Ratio – Bi-State generally supports CMS’ proposal to establish minimum medical loss ratio requirements for Medicaid and CHIP MCOs effective January 2017, and to make these requirements as consistent as possible with those for Marketplace and MA plans.

2. Standard Contract Provisions

Bi-State supports CMS’ efforts to update, expand, and reorganize the regulations around standard provisions for MCO contracts. The following provisions will be particularly beneficial in terms of both program oversight and ensuring that beneficiaries have appropriate access to care:

§438.3(a) and §438.7(a) - Timeline for submitting MCO contracts and rates for CMS review

Bi-State supports CMS’ proposal to require states to submit final contracts to CMS for review and approval no later than 90 days before the planned effective date. This proposal will ensure that CMS has adequate time to review contracts and request appropriate revisions prior to beneficiaries being enrolled under the contract.

§438.3(s)(1) - Requiring MCOs to cover medically-necessary outpatient drugs that are not included in their formularies

Bi-State supports CMS’ proposal to require MCOs who provide prescription drug coverage to cover drugs that are not included on their formulary under a prior authorization process, provided that the drug has been demonstrated to be medically necessary. This protection is critical for individuals whose medical situation makes it inadvisable for them to take the formulary drug.

§438.3(s)(1) – Timelines for responding to requests for prescriptions requiring prior authorization

Bi-State supports CMS’ proposal to require MCOs to respond a request for prior authorization for a covered outpatient drug within 24 hours of the request and dispense a 72 hour supply of a covered outpatient drug in an emergency situation. These provisions will be highly beneficial for individual with urgent medical needs.

§438.3(s)(3) – Interaction of 340B and Medicaid Managed Care

Please note that NACHC co-signed a separate letter in conjunction with the 340B Coalition which outlines these issues in detail and Bi-State supports. In this letter, we provide a brief overview of those comments.

For many FQHCs, the 340B Drug Discount Program is critical to their financial stability. As a result, any policies or practices that restrict their long-standing ability to provide 340B drugs to their patients threaten their ability to keep their doors open. This is particularly true for policies involving Medicaid

Bi-State Primary Care Association Comments

RE: Proposed Rule for Medicaid and CHIP Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; 80 Fed. Reg. 31098 (June 1, 2015)

July 27, 2015

Page 6

managed care patients, as almost half of all FQHC patients are Medicaid beneficiaries, and of these, well over half are in MCOs.

In the Affordable Care Act (ACA), Congress expanded the Medicaid Drug Discount program to Medicaid MCO patients. However, when doing so, Congress explicitly recognized and protected the important role that 340B plays for safety net providers such as FQHCs. It did so by explicitly excluding drugs purchased under 340B from the Medicaid rebates that were being expanded to other MCO drugs².

Unfortunately, in the five years since the ACA was enacted, there have been no regulations (and only one small piece of sub-regulatory guidance) published to help clarify how this new ACA language interacts with long-standing 340B policy and practice. Given this void, some states and MCOs have imposed requirements that, perhaps unintentionally, are contrary to Congressional intent behind both the 340B and ACA laws. In addition, some MCOs and states have identified creative strategies for ensuring that the benefits of the 340B program accrue to them, as opposed to the safety net providers for whom Congress intended them.

The Health Resources and Services Administration (HRSA) has tried to provide clarity on these issues and crack down on many of these creative strategies. However, they lack the statutory or regulatory authority to do so. Fortunately, CMS has the authority to address these issues, and this regulation provides the appropriate vehicle. Bi-State appreciates that in §438.3(s)(3), CMS provides some clarity by explicitly stating that 340B providers are not legally responsible for protecting manufacturers from having to pay both a 340B discount and a Medicaid rebate on a managed care claim. However, there are still numerous issues where further official guidance is needed to ensure that practices on-the-ground conform to Congressional intent. Therefore, we ask that CMS expand this section to include language that will:

- Reiterate and protect FQHCs' (and other 340B providers') statutory right to use 340B drugs for MCO patients, and
- Prohibit practices that effectively transfer the benefits of 340B from the safety net providers (as Congress intended) to a private MCO or state.

Specifically, Bi-State requests that CMS add language to the preamble and regulatory text to:

- Clarify that neither states nor MCOs may prohibit 340B providers who are in MCO networks from using 340B drugs for their patients;
- Clarify that neither states nor MCOs may require providers to agree not to use 340B drugs to their patients as a condition of participating in an MCO's network;
- Prohibit MCOs from paying lower rates for drugs purchased by 340B covered entities than for the same drugs when purchased by other MCO network providers. Similarly, states should be prohibited from requiring MCOs to pay lower rates for drugs purchased by 340B covered entities than for the same drugs when purchased by other MCO network providers; and
- prohibit MCOs from requiring 340B providers to use a methodology for identifying 340B claims that makes it highly difficult or impossible for these providers and their contract pharmacies to use 340B for Medicaid MCO patients.

² 42 USC §256b(a)(5)(A)(i).

Bi-State Primary Care Association Comments

RE: Proposed Rule for Medicaid and CHIP Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; 80 Fed. Reg. 31098 (June 1, 2015)

July 27, 2015

Page 7

With regards to the last bullet, some states and MCOs currently require providers to use specific methodologies for identifying 340B claims, and some of these methodologies are making it difficult or impossible for 340B providers to use 340B drugs for their patients. For example, pharmacies that use a virtual 340B inventory normally do not know at the point-of-sale (POS) if a claim is 340B, so requiring them to identify all 340B drugs at POS effectively prohibits these providers from using 340B drugs for MCO patients.

In addition, Bi-State offers the following comments on the interaction of the 340B and Medicaid Managed Care programs:

- Bi-State appreciates that CMS explicitly states that 340B providers are not legally responsible for protecting manufacturers from having to pay both a 340B discount and a Medicaid rebate on a managed care claim. We believe that this interpretation is consistent with the statute, and also is logical from an operational standpoint. However, since there has been some confusion in the field on this issue, Bi-State appreciates CMS addressing it explicitly in the regulation.
- CMS should permit 340B providers to report claims data directly to the state or the states' rebate contractor, bypassing the MCOs. For some states, it may be more efficient and cost-effective for 340B providers to report their claims data directly to the state or its rebate contractor, instead of MCOs. For example, some MCOs do not possess the technical capability to handle reporting, and/or do not have the necessary relationships with entities to develop successful reporting mechanisms. While this approach may not be appropriate for all states, we recommend that CMS grant states the flexibility to pursue the option if they deem it most appropriate. Any state-created methodology should also allow covered entities to carve in or out on an MCO-by-MCO basis. We note that Oregon is currently using a system that bypasses the MCOs.
- CMS should require MCOs to use separate Bank Identification Numbers (BINs) and Processor Control Numbers (PCNs) for their Medicaid plans and to share these BIN-PCNs with 340B Covered Entities. BIN/PINs are used in combination to process electronic pharmacy claims. Some MCOs use a single BIN/PCN combination for both their Medicaid and commercial lines of business. This poses a problem for 340B providers because the pharmacy cannot distinguish between Medicaid and commercial claims. If the entity has chosen to use 340B drugs for Medicaid managed care patients, the pharmacy would have to identify more claims than needed as 340B, which could be burdensome depending on the reporting mechanism. If an entity decided to not use 340B for Medicaid managed care patients, the entity would have to exclude more claims than necessary, losing out on 340B savings for non-Medicaid commercially insured individuals. To address this issue, CMS should require MCOs to use unique BIN/PCN combinations for their Medicaid Plans and to share the combinations with covered entities. We note that Minnesota Medicaid has already instituted such a requirement for its MCOs.
- CMS should prohibit MCOs from using billing information from 340B Medicaid claims to reduce reimbursement for 340B commercial claims. CMS should require MCOs to develop a firewall between their Medicaid and commercial lines of business to prevent an MCO from using billing information obtained from 340B Medicaid claims to lower their reimbursement for 340B commercial claims. A commercial reimbursement rate for 340B drugs that is very low relative to an MCO's standard rate would exhaust much of the 340B savings that Congress intended these providers receive when it created the 340B program. Congress did not create the 340B program to operate as a financial pass through from pharmaceutical manufacturers to third-party payers. As such, an MCO's reduced commercial reimbursement rates to 340B

Bi-State Primary Care Association Comments

RE: Proposed Rule for Medicaid and CHIP Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; 80 Fed. Reg. 31098 (June 1, 2015)

July 27, 2015

Page 8

providers would contravene Congressional intent and frustrate the purpose of the 340B program.

3. Setting Actuarially Sound Capitation Rates for Medicaid Managed Care Programs

Bi-State strongly supports CMS' efforts to update the regulatory structure for MCO rate setting to ensure increased consistency and transparency, thereby strengthening beneficiary access. We also support efforts to ensure that capitation rates are set at levels that are actuarially sound, and include payment only for those costs that are appropriate for the MCO to pay. In this section, we ask CMS to reinforce its long-standing policy specifying which FQHC-related costs are appropriate for inclusion in actuarially sound capitation rates.

3b. Actuarial soundness standards (§438.4) (also §438.60)

§438.4(a) – Appropriate costs to include in actuarially sound capitation rates

Section §438.4(a) defines actuarially sound capitation as rates that are “projected to provide for all reasonable, *appropriate*, and attainable costs that are required under the terms of the contract...” (emphasis added). As will be explained in detail below, longstanding CMS policy have made it clear that the only FQHC-related costs that are appropriate to include when calculating actuarially sound capitation rates are those for payments that are at the same rate as payments to a similar provider offering the same services.

In addition to receiving reimbursement from MCOs at market rates, FQHCs are also entitled to supplemental payments, equal to the difference between the amount they receive from the MCO and their Prospective Payment System (PPS) or Alternative Payment Methodology (APM) rates. State obligations to provide for full and fair payment to FQHCs in the managed care context have been emphatically stated by numerous courts.³ Per §1902(bb)(5)(A), these payments must be made “by the State,” rather than by the MCO.

In recent years, some states have sought to require MCOs to pay FQHCs in their network the full PPS/APM amount, and to incorporate the full PPS/APM rate into MCOs' actuarially sound capitation rates. The following section outlines why this practice is contrary to statute, long-standing policies, and recent court decisions, and should be explicitly prohibited under this regulation.⁴

³ For example, the U.S. Court of Appeals for the Third Circuit has held: “By opting into a managed care system, the State cannot avoid its responsibility to reimburse FQHCs at the full PPS amount. Rather, Section 1396a(bb)(5)(B) requires the State to ‘pay FQHCs fully compensatory supplemental payments not less frequently than four months after [the State] has received the [FQHC’s] claim for supplemental payment.’” *New Jersey Primary Care Ass’n, Inc. v. New Jersey Dep’t of Human Services*, 722 F.3d 527, 541 (3d Cir. 2013) (citing *Three Lower Counties Cmty. Servs v. State of Maryland*, 498 F.3d 294, 303, (4th Cir. 2007)). The court went on to state: “[W]hile the statutory language is perhaps not as clear as one would wish, the tenor of the subsequent interpretations and the limited case law is clear: where MCOs do not pay out valid Medicaid claims, the FQHC should not be left holding the bag.” *Id.*

⁴ “The fundamental shortcoming with the Supplemental Payment Program and Complaints Policy [of New York State] is that together these policies make the MCO the ultimate arbiter of the reimbursability of services that an FQHC provides ‘pursuant to a contract’ with an MCO. 42 U.S.C. § 1396a(bb)(5)(A). This cannot be squared with the text of Section 1396a(bb)(2), which imposes an absolute burden on the state to reimburse FQHCs for the entirety of their reasonable costs. Nor can it be squared with the clear intent of Congress to ensure that Section 330 centers do not end up subsidizing state Medicaid programs.” *Cmty. Health Care Ass’n of New York v. Shah*, 770 F.3d 129, 153 (2d. 2014).

Bi-State Primary Care Association Comments

RE: Proposed Rule for Medicaid and CHIP Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; 80 Fed. Reg. 31098 (June 1, 2015)

July 27, 2015

Page 9

Legal Background on State Responsibility to make FQHC Supplemental Payments Directly

The FQHC supplemental payment requirement under Medicaid⁵ was first implemented by Congress in the Balanced Budget Act of 1997 (“BBA”). At that time, states were required to reimburse FQHCs under Medicaid at 100 percent of their reasonable costs, and many states had already begun to move significant parts of their Medicaid programs into managed care. In order to harmonize Medicaid managed care with States’ FQHC payment obligations, Congress inserted two provisions in the Social Security Act that by design prohibited states from delegating their payment obligations to MCOs. First, states (rather than MCOs) were responsible for ensuring that FQHCs received full payment for services provided in the managed care setting. Second, states must, through the managed care contract, require MCOs to pay FQHCs an amount that is no less than the amount they would pay non-FQHC providers. *See* BBA, Pub. L. No. 105-33, § 4712(b) (Jan. 7, 1997).

The first BBA provision, the supplemental payment requirement, now located at SSA § 1902(bb)(5), requires that when an FQHC provides services under a contract with an MCE, the state shall “provide for payment to the center or clinic *by the State* of a supplemental payment equal to the amount (if any) by which the amount determined under [the FQHC’s PPS rate] exceeds the amount of the payments provided under the contract” (emphasis added). In other words, the state is obligated to make sufficient payments to the FQHC to make the FQHC whole, paying up to the difference between what an MCO paid the FQHC and the amount to which the FQHC was entitled from the state.

The second BBA provision added language that we will refer to as the “comparability requirement.” It required that the state’s contract with the MCO require the MCO to reimburse FQHCs “not less than the level and amount of payment which the [MCO] would make for the services if the services were furnished by a provider which is not” an FQHC. SSA § 1903(m)(2)(A)(ix).

CMS issued two State Medicaid Director Letters (“SMDLs”) in 1998 explaining the purpose and intent behind the two BBA provisions. In the first SMDL, issued in April 1998, CMS explained that the obligation to make supplemental payments was the state’s alone, and that “this requirement cannot and should not be delegated to an MCO . . . each State must determine any differences in payment and make up these amounts.”⁶

In that same SMDL, CMS addressed the comparability requirement. According to CMS, Congress was addressing two concerns through this requirement. First, it sought to ensure that FQHCs were on equal footing with other types of providers when entering into contracts with MCOs for Medicaid services: MCOs did not have to pay the FQHCs their (typically higher)

⁵ We note that Congress instituted an analogous supplemental payment framework for FQHCs in Medicare in the Medicare Modernization Act (“MMA”) of 2003, Pub. L. No. 108-173. The MMA established the Medicare Advantage program. In the Medicare Advantage context, the supplemental payment is owed from CMS to the health center. CMS promulgated a regulation, 422.316, providing that CMS “will pay the amount determined [under the FQHC Medicare cost-based reimbursement provisions of the Social Security Act] *directly to the FQHC* at minimum on a quarterly basis, less the amount the FQHC would receive for the MA enrollee from the MA organization. . . .” In the Medicaid context, we believe the statutory directive in SSA § 1902(bb)(5) is sufficiently explicit that no implementing regulation is necessary, but we urge CMS to reaffirm that in Medicaid, as in Medicare, the supplemental payment obligation is an obligation owed directly by the payor (here, the State) to the FQHC.

⁶ *See* April 20, 1998 SMDL, available at <http://medicaid.gov/federal-policy-guidance/federal-policy-guidance.html>.

Bi-State Primary Care Association Comments

RE: Proposed Rule for Medicaid and CHIP Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; 80 Fed. Reg. 31098 (June 1, 2015)

July 27, 2015

Page 10

Medicaid rates that were established by statute. Requiring plans to pay FQHCs their unique rate would have the potential to deter MCOs from contracting with FQHCs. Second, Congress sought to protect the states from instances in which the rates negotiated by an MCO and FQHC are lower than the market rate that would apply to other primary care providers, because then the state's supplemental payment obligation would be greater. The SMDL noted that ". . . a State has the flexibility to develop its own methodology for determining whether rates paid by MCOs to FQHCs/RHCs are not less than to other similar providers of services."

Thus, while the explicit language in the BBA only prevented an MCO from paying an FQHC less than the amount it paid non-FQHC providers, CMS concluded that the provision was in fact designed to ensure that MCOs negotiated rates of payment with FQHCs that are neither lower nor higher than rates paid to non-FQHC primary care providers. Stated otherwise, CMS interpreted the "not less than" provision, SSA § 1903(m)(2)(A)(ix), as functioning as both a floor and a ceiling on payment. On October 23, 1998 CMS issued a second SMDL⁷ on this topic. CMS clarified that the intent of the BBA provisions was to "not have the MCO involved in any issues regarding supplemental payments, reconciliation, or any other reimbursement issue that would raise payment levels" between the MCO and the FQHC to an amount higher than a similar non-FQHC provider. CMS explained: "This clarification is intended to assure that MCOs do not perceive or incur any undue burdens when contracting with FQHCs/RHCs versus other providers of care *thus creating unintended barriers or disincentives to contract*"⁸ (emphasis added).

The comparability requirement, as interpreted by CMS in the 1998 SMDLs, has a clear impact on the development of actuarially sound capitation payments for MCOs. Specifically, the state's capitation payment to the MCO may take into account only the general market rate dictated by the comparability requirement. If the full PPS rate were factored into the capitation rate, then the state would be transferring its supplemental payment obligation to the MCO, risking the very outcomes that CMS stated in the 1998 SMDLs were contrary to Congressional intent.

Although the 1998 SMDLs preceded the implementation of the PPS methodology in 2001, the reasoning in those documents still applies to the current FQHC reimbursement system. Of particular note, when Congress amended the FQHC payment methodology to implement PPS in 2001, the law included a supplemental payment provision identical in all material respects to the one that had been enacted in 1997. *See Consolidated Appropriations Act, 2001, Pub. L. No. 106-554, App. F, § 702.* In addition, the provisions on FQHC reimbursement in CMS's 2003 "actuarial checklist" used to evaluate managed care contracts – the "[Financial Review Documentation for At-Risk Capitated Contracts Ratesetting](#)" incorporate the standards stated in the 1998 SMDLs. The checklist provides, in cell AA.3.9: "The State may build in only the FFS rate schedule or an actuarially equivalent rate for services rendered by FQHCs and RHCs. The State may NOT include the FQHC/RHC encounter rate, cost-settlement, or prospective payment amounts. The entity must pay FQHCs and RHCs no less than it pays non-FQHC and RHCs for similar services. In the absence of a specific 1115 waiver, the entity cannot pay the annual cost-settlement or prospective payment."

⁷ Also available at <http://medicaid.gov/federal-policy-guidance/federal-policy-guidance.html>.

⁸ *See* October 23, 1998 SMDL, available at <http://medicaid.gov/federal-policy-guidance/federal-policy-guidance.html> (emphasis added).

Bi-State Primary Care Association Comments

RE: Proposed Rule for Medicaid and CHIP Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; 80 Fed. Reg. 31098 (June 1, 2015)

July 27, 2015

Page 11

Despite this legal and policy history, a growing number of states are now inappropriately including the full FQHC payment amount in their actuarially sound capitation rates, thereby delegating to MCOs their legal responsibility to make supplemental payments to FQHCs directly. While this issue is now being addressed through the courts, pursuing a judicial resolution is both time-consuming and labor-intensive for FQHCs. Therefore, Bi-State asks that CMS clarify this issue in this regulation, as discussed below.

Section §438.4(a) defines actuarially sound capitation as rates that are “projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract...” As discussed above, CMS has clearly stated that MCOs are to reimburse FQHCs at rates that are neither lower nor higher than rates paid to non-FQHC primary care providers for similar services, so only costs associated with these rates are appropriate for including in the rate calculation. Bi-State requests that CMS reaffirm its conclusions in the two 1998 SMDLs described above by:

- §438.4(a) – In the preamble discussion of which costs are appropriate to include when calculating actuarially sound capitation rates, clarify that the only FQHC-related costs that are appropriate for inclusion are those for payments made at the same rate as payments to similar providers.

§ 438.60 - Exceptions to the regulatory prohibition on duplicate payments

Section 438.60, as published in 2002, seeks to avoid duplicate payments for the same service by prohibiting state agencies from making payments directly to managed care network providers for services covered under a managed care contract. However, the regulations contain an exception allowing direct payments by the state agency to network providers where those payments are explicitly required by federal law.

In the preamble to the 2002 Final Rule, CMS explained that this exception was intended to apply “to two types of providers—disproportionate share hospitals (DSH) and Federally qualified health centers (FQHCs).” CMS noted that the Social Security Act “specifically requires direct payments to these providers when they are part of an MCO provider network.”⁹ Bi-State requests that this clarification be repeated in the preamble to the new rule, as follows:

- § 438.60 - In the preamble discussion of exceptions to the regulatory prohibition on duplicate payments to MCO network providers, state that as stated in the 2002 Rule, supplemental payments to FQHCs are one of the two types of payments to which this exception applies.

In addition, we request that CMS reiterate the statutory requirement, supported by case law and SMDLs, that the state is legally responsible for ensuring that appropriate supplemental payments are made directly to FQHCs, and that this legal responsibility may not be delegated to MCOs. (Note that, in Bi-State’s view, states may delegate the administrative responsibility for making these payments to MCOs, but only if a state ensures that a retroactive reconciliation process is implemented to ensure that

⁹ In the preamble to the 2002 Final Rule, CMS referred to the supplemental payments to FQHCs as being required by SSA § 1902(a)(13). 67 Fed. Reg. 40989. This appears to be an error, as the Consolidated Appropriations Act, 2001, Pub. L. No. 106-554, App. F, § 702, amended the Social Security Act effective January 1, 2001 to delete the provision of § 1902(a)(13) addressing FQHC reimbursement and to add a new § 1902(bb), introducing the FQHC prospective payment system (PPS). The supplemental payment requirement dated from the Balanced Budget Act of 1997, Pub. L. No. 105-33, and the 2001 amendments made only minor changes to the supplemental payment provision.

Bi-State Primary Care Association Comments

RE: Proposed Rule for Medicaid and CHIP Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; 80 Fed. Reg. 31098 (June 1, 2015)

July 27, 2015

Page 12

MCOs are properly reimbursed for their costs based on actual – as opposed to projected – FQHC utilization. This approach should: reduce the administrative effort for states; ensure that MCOs are not at financial risk if actual utilization differs from projections; and eliminate any disincentives for MCOs to send patients to FQHCs.) Therefore, Bi-State recommends:

- § 438.60 - In the preamble discussion, state that states are legally responsible for ensuring that appropriate supplemental payments are made to FQHCs, and this legal responsibility may not be delegated to an MCO.

3d. Special Contract Provisions Related to Payment

§438.6(c) - Value-Based Purchasing Models

Under § 438.6(c), CMS proposes to allow states to require MCOs to “implement value-based purchasing models for provider reimbursement, such as pay for performance arrangements, bundled payments, or other service payment models intended to recognize value or outcomes over volume of services.” CMS explains that it wants to “encourage states to use health plans as partners to assist the states in achieving overall delivery system and payment reform and performance improvements.”

While Bi-State generally supports the provisions of subsection (c), it is important to note that health centers have unique limitations when participating in risk arrangements and value-based purchasing programs. These limitations are due to statutory and programmatic requirements under the Health Center program (Section 330 of the Public Health Service Act, or PHSA). Health centers must fulfill those requirements as a condition of their HRSA grant funding or look-alike (“LAL”) status, and health center grantee or LAL status in turn is a prerequisite to qualifying as an FQHC under Medicaid. Specifically, health centers are prohibited from using any grant funds received under Section 330 to help support any services that are outside of their approved “scope of project.”¹⁰ As health centers’ scope of project are generally limited to primary and preventive care, Section 330 funding cannot be used to offset the costs of specialty, hospital, or other types of care. HRSA has also stated that supplemental payments from the state under managed care are not intended to cover costs for specialty or inpatient care.¹¹ As a result, HRSA has recognized that health centers must be exceptionally careful when entering into risk arrangements, as doing so could place their Section 330 funding, and status as an FQHC, at risk. Given these unique funding and operational restrictions, Bi-State makes the following requests to CMS:

- In recognition of the unique requirements faced by FQHCs, do not permit states or MCOs to require FQHCs to accept risk for services beyond primary and preventive care as a condition of joining a MCO network. Specifically:
 - Add a subparagraph (G) at the end of the list of conditions for CMS approval of MCO agreements in §438.6(c)(2)(i). This subparagraph should read: “Does not require

¹⁰ A Section 330 health center’s “Scope of Project” defines the activities and locations that can be supported by the total approved budget for all funds awarded. The total approved budget for a health center includes grants funds, program income, and other non-section 330 related funds pledged to the scope of project. For a more information on health center scope of project and related budgeting and accounting, see Health Resources and Services Administration (HRSA), *Policy Information Notice #2013-01* (updated Mar. 18, 2014), <http://bphc.hrsa.gov/policiesregulations/policies/pdfs/pin201301.pdf>.

¹¹ See Letter from Jim Macrae, Assoc. Administrator, Bureau of Primary Care, Department of Health and Human Services, to Health Center Directors, Commonwealth of Puerto Rico (Feb. 22, 2011) - appended at the end of these comments.

Bi-State Primary Care Association Comments

RE: Proposed Rule for Medicaid and CHIP Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; 80 Fed. Reg. 31098 (June 1, 2015)

July 27, 2015

Page 13

FQHCs to assume risk for services beyond primary and preventive care as a prerequisite for obtaining a managed care provider agreement.”

- o Add a subparagraph (iv) under §438.6(c)(1) stating that the state may not require FQHCs to assume risk for services beyond primary and preventive care as a prerequisite for obtaining a managed care provider agreement.”

State requirement on MCO expenditures

- § 438.6(c)(1) – Clarify that states may impose additional requirements on MCO expenditures beyond those in this section, if those requirements are statutorily mandated.

Section 438.6(c)(1) states “Except as specified in paragraphs (c)(1)(i) through (iii) of this section [concerning value-based purchasing and minimum pay schedules and fee increases for providers], the state may not direct the MCO’s, PIHP’s, or PAHP’s expenditures under the contract.” Bi-State is concerned that subparagraphs (i) through (iii) could be misinterpreted as a complete list of the permissible limitations states can impose on MCOs’ expenditures. This overlooks the fact that the state’s contract must direct the MCO’s expenditures to the extent that such expenditures are mandated under the statute and related regulations. One example of this type of requirement is payment levels for FQHCs, as discussed above.

To avoid this potential misinterpretation, Bi-State recommends that CMS add the italicized language to subparagraph 438.6(c)(1). “Except as specified in paragraphs (c)(1)(i) through (iii) of this section *or as otherwise specifically required by statute*, the state may not. . . .”

Clarify in the preamble that an FQHC’s participation in risk-based or value-based purchasing arrangement has no impact on the supplemental payment obligation that the state owes directly to the health center. As described in detail above, supplemental payment obligations are prescribed in Title XIX of the SSA and should not be impacted by the proposed rule.

4. Other Payment and Accountability Improvements

4a. Prohibition of Additional Payments for Services Covered under MCO, PIHP, or PAHP Contracts (§438.60)

Please see detailed comments under 3b. Actuarial soundness standards (§438.4).

4c. Program Integrity

§ 438.608(a)(8) – Payment Suspensions in cases of “Credible Allegations of Fraud”

§ 438.608(a)(8) of the NPRM requires MCOs to suspend payments to providers “for which the State determines there is a credible allegation of fraud” (unless the state determines that there is a good cause not to suspend them). This provision implements in the managed care setting the payment suspension regulations which were implemented in the fee-for-service (FFS) setting in 2011.

Since 2011, many Medicaid providers, and ultimately, their patients, have faced considerable challenges as a result of overzealous implementation of these provisions on the part of some states, as

Bi-State Primary Care Association Comments

RE: Proposed Rule for Medicaid and CHIP Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; 80 Fed. Reg. 31098 (June 1, 2015)

July 27, 2015

Page 14

well as Federal regulations that give providers relatively little information about the process or opportunities to defend themselves.

For example, the 2011 regulation provides a very expansive definition of what constitutes a “credible allegation of fraud.”, The regulation gives states significant latitude to define a “credible allegation”; in the preamble to the 2011 rule, CMS stated that the “threshold level of certainty or proof necessary to identify” an allegation of fraud was lower than previous standards for payment withholds. See 76 Fed. Reg. at 5932. Some states have implemented very broad definitions (e.g., suspending payments as a result of billing errors or disputes in which no fraud was alleged) resulting in overzealous implementation of this authority. For example, a commission of Texas state legislators found that the Texas OIG had gone beyond the law’s intent to use payment suspensions as an enforcement tool in only serious matters. The Commission recommended that the Texas legislature rein in the Texas OIG’s authority and update the statutory definition of fraud to clarify that it does not include unintentional technical, clerical, or administrative errors.¹² This overzealous implementation has direct, negative impacts on Medicaid providers, and ultimately, their patients. Even state agencies have acknowledged this directly – see [this quote](#) from a state attorney in New Mexico.

In addition, Federal regulations give providers relatively little information or opportunities to defend themselves once they are accused of fraud. Under the 2011 regulation, Medicaid agencies may immediately suspend payments before the provider is notified of the suspension. Moreover, while the state Medicaid agency is required to provide written notice of the suspension, it “need not disclose any specific information concerning an ongoing investigation;” this lack of information makes it difficult for providers to adequately defend themselves in a timely manner. In addition, even if they had this information, providers whose payments are suspended have only limited opportunities to respond to the suspension.

Finally, providers have experienced Medicaid payment suspensions that have gone on indefinitely, without adequate due process, while the state delays a final determination as to the allegation of fraud. Payment suspensions are challenging for all providers, but are particularly troubling for health centers due to health centers’ unique service obligations. In general, a suspended provider must determine whether to assume payment losses for Medicaid patients or stop accepting Medicaid patients. But under Section 330 of the PHSA, health centers must treat all patients regardless of insurance status or ability to pay. A health centers subject to a payment suspension has no choice but to continue seeing Medicaid patients when Medicaid payments are suspended, jeopardizing its operations.

Given these concerns, Bi-State recommends that CMS revise its proposed 42 C.F.R. § 438.608(a)(8) to incorporate the following protections for providers:

- Require the state to notify the MCO of a pending investigation of a credible allegation of fraud;
- Require that these notifications be in writing, be certified by an appropriate state official, and contain enough detailed information for the provider to respond to the specific allegation;

¹²See Sunset Advisory Commission, *Staff Report with Commission Decisions on Health and Human Services Commission and System Issues* (Dec. 2014),

https://www.sunset.texas.gov/public/uploads/files/reports/HHSC%20and%20System%20Issues%20Commission%20Decisions_Revised%20January%202015.pdf.

Bi-State Primary Care Association Comments

RE: Proposed Rule for Medicaid and CHIP Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; 80 Fed. Reg. 31098 (June 1, 2015)

July 27, 2015

Page 15

- Require the state to recertify to the MCO and provider at regular intervals (e.g., every ten days) that the fraud investigation is ongoing; and
- Require MCOs to process suspended payments to a provider on a timely basis once the allegation has been resolved in favor of the provider (e.g., within three days following notification from the state). Establish a maximum length of time for which the state and MCO can suspend payments prior to making a final determination as to the credible allegation of fraud.

5. Beneficiary Protections

Bi-State strongly supports CMS' numerous proposals to strengthen the beneficiary protections under managed care. In this section, we express our support for provisions and offer one specific comment for how to further strengthen these protections, while also furthering the goal of aligning Medicaid managed care with Marketplace and MA plans. We also list several provisions which we consider to be extremely beneficial.

5a. Enrollment

- §438.54(c)(2) and (d)(2) – Strong support for “choice period” of at least 14 days. Bi-State strongly supports CMS' proposal to require states to provide a period of at least 14 calendar days of FFS coverage for potential enrollees to make an active choice of their managed care plan. This time period will be extremely valuable for many underserved populations, including but not limited to: individuals who are unfamiliar with managed care; those with limited literacy or English proficiency; and those unable to access MCO materials on-line. While a period longer than 14 calendar days would be preferable, we strongly encourage CMS maintain no less than 14 days as a minimum requirement.
- §438.54(c)(3)(ii) and (d)(3)(ii) - Support for adding 3 days for delivery. Bi-State supports the proposal to require the MCO enrollment have a postmark or electronic date stamp that is at least 3 calendar days prior to the first day of the 14-day choice period. This provision will be particularly helpful to individuals who do not have reliable access to the Internet.

5c. Beneficiary Support System

§ 438.71(c)(2) Choice Counseling should build on the existing network of Marketplace Assisters

- Establish “one-stop shopping” for low-income persons to receive Choice Counseling (CC) by permitting organizations that receive Federal and/or state support to provide similar services under the Marketplace to provide state-supported CC under Medicaid managed care, without being registered as enrollment brokers.

Bi-State applauds CMS for proposing to expand the role and availability of Choice Counseling (CC) for Medicaid beneficiaries. However, we are concerned that CMS is proposing to retain the current regulatory requirement that organizations who provide CC services under a Memorandum of Agreement or contract with the state (which we refer to as “state-supported CC”) must be registered as enrollment brokers. Failure to update this requirement would prohibit much of the existing network of Choice Counselors under the Marketplace from being able to provide state-supported CC services to Medicaid beneficiaries, creating inefficiencies, a lack of alignment across programs, and unnecessary hassles for patients.

Bi-State Primary Care Association Comments

RE: Proposed Rule for Medicaid and CHIP Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; 80 Fed. Reg. 31098 (June 1, 2015)

July 27, 2015

Page 16

In the preamble, CMS states that expanded CC is meant to be similar to the type of “personalized assistance” provided in “existing programs in the Marketplaces.” In fact, the regulatory definition is very similar to the definition of assister services provided via the Marketplace – both in terms of what services must be provided (e.g., identifying factors to consider when choosing among managed care health plans and primary care providers) and which ones must not (e.g., making recommendations for or against enrollment into a specific MCO.) In addition, CMS acknowledges that many individuals frequently churn between Medicaid, the Marketplace, and being uninsured, and that one of the central goals of this regulation is to align these programs as much as possible. For these reasons, CC services provided by the state for its Medicaid MCE patients should be as coordinated as possible with the existing infrastructure for providing these services to potential Marketplace enrollees.

However, as currently drafted, the regulation excludes many current Marketplace assisters from providing state-supported CC services to Medicaid MCE beneficiaries, because they are not enrollment brokers. In particular, failure to update this requirement would exclude FQHCs, which constitute the largest and broadest network of enrollment assisters in the country. As documented in a [Kaiser Foundation report](#), as part of the first ACA open enrollment period, FQHCs received over \$200 million in grant funding to provide Marketplace assistance and operated in every Marketplace. (In contrast, states committed roughly \$100 million for in-person assisters, and CMS awarded \$67 million in Navigator grants.) For the second open enrollment period, funds for FQHCs remained stable while funds for in-person assisters and Navigators decreased. Through the use of these and other funding sources, FQHCs provided approximately 5 million “assists” during the 2013-2014 open enrollment period.

From the patient perspective, such coordination between Medicaid and Marketplace CC counselors is critical to providing a “one-stop shopping” experience. When many patients first seek enrollment assistance, they do not know whether they will qualify for Medicaid, a subsidized Marketplace plan, or neither. Under the current proposal, many of these individuals will go to an assister funded through the Marketplace (e.g., FQHC, Navigator, IPA), and if they are found to be eligible for a Marketplace plan, they can receive assistance in evaluating their options on-the-spot. However, if they are found eligible for a Medicaid managed care, they will be required to go elsewhere to receive similar support in evaluating their options. This is not only inefficient, but also contrary to the “no wrong door” and “patient experience” goals that CMS has worked so diligently to implement since the enactment of the ACA.

In addition, excluding FQHCs and other experienced Marketplace assisters from providing state-supported CC to Medicaid enrollees is inefficient in terms of both time and resources, because it fails to build on existing structures that target many of the same patients. And finally, it is inconsistent with one of the central goals of this NPRM, which is to align practices across Medicaid, the Marketplace, and MA. For all these reasons, Bi-State strongly encourages CMS to make all organizations who receive state or Federal support (in the form of funding or recognition) to provide CC-type services under the Marketplace eligible to receive state support to serve the same role for Medicaid managed care patients, without having to be enrollment brokers.

- For state-supported CC providers who are not enrollment brokers, ensure that appropriate conflict-of-interest protections are in place. Also, clarify that serving as a network provider for a health insurer does not constitute a conflict of interest provided that appropriate safeguards (such as those used in the Marketplace) are in place.

Bi-State Primary Care Association Comments

RE: Proposed Rule for Medicaid and CHIP Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; 80 Fed. Reg. 31098 (June 1, 2015)

July 27, 2015

Page 17

Bi-State appreciates CMS' concern about potential conflicts of interest if CC is provided by providers who participate in MCE networks. However, this was also a concern for FQHCs and other community-based providers offering CC services to Marketplace enrollees, and in the Marketplace context, effective limitations were put in place to prevent such conflicts. (For example, while FQHC assister staff may explain the factors that enrollees should consider when choosing a plan, they are not permitted to recommend a specific plan, or to actually select the plan on the enrollee's behalf. In addition, under the in-person assister conflict-of-interest rules, entities that are health insurance plans or that receive payment from health insurance plans for enrolling individuals in the plan may not serve as in-person assisters. *See* 45 C.F.R. § 155.210(d).) Similar protections could be put in place regarding Medicaid CC, thereby enabling states to build upon the existing network of FQHCs and other community-based enrollment assisters who target underserved populations.

- If unwilling to modify the provisions as described above, at a minimum CMS should state in the preamble that states are permitted to contract with entities other than enrollment brokers to perform the portions of “beneficiary support system” other than “choice counseling.” This would include assisting enrollees in understanding managed care. Also, CMS should clarify in the preamble that FFP for administrative costs is available for such a contract.

5g. Managed Long-Term Services and Supports

§ 438.214(b) –Credentialing and Recredentialing Requirements

This section requires each state to establish a uniform credentialing and recredentialing policy, and require each MCO to follow these policies. Subsection (c), entitled “Nondiscrimination,” states that MCO provider selection policies and procedures must not discriminate against providers that serve high-risk populations or specialize in conditions that require costly treatment.

Bi-State supports the overall goals of consistency and nondiscrimination in selection of MCO network providers, including through the credentialing process. However, FQHCs are already required by federal law and policy to conduct an independent credentialing process for all licensed independent practitioners. This process must include verification of the clinician's current licensure; relevant education, training, or experience; current competence; and health fitness, or the ability to perform the requested privileges. For detailed information on this process, see HRSA Policy Information Notice (PIN) 2001-16, Credentialing and Privileging of Health Center Practitioners (July 17, 2001); and PIN 2002-22, Clarification of PIN 2001-16 (July 1, 2002).¹³

Specifically, PHSa §224 provides medical malpractice coverage under the Federal Torts Claims Act (FTCA) to health centers that are funded under PHSa §330 when the health center successfully applies for and is deemed to be covered under FTCA by HRSA. As part of the deeming application and requirements for FTCA coverage, health centers must conduct thorough credentialing of providers. HRSA implements these credentialing requirements through periodic updates of policy, and closely oversees health center credentialing through numerous methods, including: the FTCA deeming and re-deeming applications; regularly-scheduling operational site visits; Project Officer oversight of health

¹³ Health centers that receive grant funds under Section 330 of the PHSa and that apply for “deemed” status so that their clinicians may obtain malpractice coverage under the Federal Tort Claims Act (FTCA) are required to institute a credentialing process as a prerequisite for FTCA deeming, *see* 42 U.S.C. § 223(h)(2); however, the requirement to have a credentialing process applies more broadly to all community health centers, migrant health centers, health care for the homeless grantees, and FQHC look-alikes. *See* HRSA PINs 2001-16, 2002-22.

Bi-State Primary Care Association Comments

RE: Proposed Rule for Medicaid and CHIP Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; 80 Fed. Reg. 31098 (June 1, 2015)

July 27, 2015

Page 18

centers, and other monitoring mechanisms.¹⁴ This formalized, legally mandated, and Federally-monitored clinician credentialing process that FQHCs must follow in order to pursue FTCA deeming is unique.

Given the thorough nature of this mandated credentialing process, as well as the degree and regularity of Federal oversight of the process, Bi-State thinks that imposing a state-mandated process on FQHCs, which must be implemented separately for each clinician for each MCO, is unnecessarily duplicative. In contrast, when Medicaid MCEs delegate the credentialing function to FQHCs, it is efficient and beneficial for all parties involved. The MCE is spared the administrative costs associated with clinician credentialing; the state and federal governments are spared duplicative costs; and health centers are able to serve patients and access MCO reimbursements promptly without being hobbled by delays occasioned by the MCE's clinician credentialing process.

For these reasons, Bi-State requests that CMS:

- Clarify in the preamble on section § 438.214(b) that because FQHCs are already required by statute and HRSA policy to conduct credentialing for each licensed independent practitioner providing services on behalf of the health center:
 - States should permit and encourage MCOs to delegate credentialing of clinicians to FQHCs and
 - Such delegation is not inconsistent with the requirement to establish a “uniform credentialing and recredentialing policy” under paragraph (b)(1) and does not run afoul of the nondiscrimination requirement.

In addition, health centers are very concerned about the length of time that some MCOS take to process completed credentialing applications, and the impact that these delays have on their financial stability. In many states, it is not uncommon for MCOS to take up to 18 months to process a complete credentialing application. During this waiting period, providers are not eligible for reimbursement from the MCO, even if they are providing care for that MCOs' patients. In addition, once an application is finally approved, many MCOs do not pay these providers retroactively, or if they do make retroactive payments, they are generally limited to a short period. For example, in South Carolina, many FQHCs will wait 18 months (from the date that they submitted a complete application) for approval, but only be given retroactive payments for 3 months.

While these extended delays and lack of retroactive reimbursement are problematic for all Medicaid providers, they are particularly problematic for health centers. As previously stated, other types of providers may turn away Medicaid patients during this waiting period, and thereby avoid incurring costs for which they will not be reimbursed. However, health centers are required by statute to serve all individuals, and therefore are forced to absorb the full costs of caring for the MCO's patients while they are waiting for the MCO to approve their providers' applications. (Note that, as discussed above, these providers have already completed a thorough, federally-mandated and Federally-monitored credentialing process.)

¹⁴ For more detail on HRSA policies governing credentialing and privileging, see Health Resources and Services Administration (HRSA), *Policy Information Notice #2002-22* (updated Oct. 30, 2014), <http://bphc.hrsa.gov/programrequirements/pdf/pin200222.pdf>; HRSA, *Policy Information Notice #2001-16* (July 17, 2001), <ftp://ftp.hrsa.gov/bphc/docs/2001pins/2001-16.pdf>; and HRSA, *Health Center Program Site Visit Guide* (Nov. 2014), <http://bphc.hrsa.gov/administration/visitguidepdf.pdf>.

Bi-State Primary Care Association Comments

RE: Proposed Rule for Medicaid and CHIP Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; 80 Fed. Reg. 31098 (June 1, 2015)

July 27, 2015

Page 19

The present regulatory structure provides no incentives for MCOs to review and approve credentialing applications in a timely manner. In contrast, by setting no requirements around timeframes or retroactive payments, it creates an incentive for MCOs to delay approving applications as long as possible. This is because the longer the MCO takes to approve an application, the more costs it can shift to the health center (and/or other providers who are willing to care for the MCO's patients without reimbursement.) This in turn enables the MCO to keep more of the capitation rate for itself. For these reasons, while MCO policies for approving credentialing applications may seem like an insignificant administrative issue, they have significant implications for the financial stability of health centers and other providers who accept all patients regardless of ability to pay.

For these reasons, Bi-State strongly recommends that:

- To offset financial incentives for MCOs to delay approving credentialing applications, CMS should:
 - Require MCOs to publicly report (on the state website, etc.) the average length of time they take the process credentialing applications, starting from the date that a complete application package is received.
 - Require MCOs to make payments to credentialed providers retroactive to the date that their completed credentialing application was received.

6. Modernize Regulatory Requirements

6a. Availability of Services, Assurances of Adequate Capacity and Services, and Network Adequacy Standards

§438.68 – Network Adequacy Standards

Bi-State strongly supports CMS' efforts to strengthen the network adequacy (NA) standards for MCOs. We specifically support CMS' proposals to:

- Create a new §438.68 specific to the development of network adequacy standards
- Ensure ongoing state assessment, certification, and reporting of the adequacy of MCO networks
- Outline factors to be "considered" when establishing these standards
- Require network adequacy standards for a specified set of providers, particularly primary care and OB/GYN
- Ensure that MCOs' network adequacy standards are easily available and transparent.

While Bi-State supports all of CMS' proposals in this area, we feel strongly that they do not go nearly far enough. While they require states to establish and enforce NA standards - including distinct standards for specific provider types - there are no required minimums for these standards. As a result, states can set these requirements at levels that are far below what is needed to truly provide appropriate access to services. Also, while the proposed regulatory text outlines factors to be "considered" when establishing these standards, the term "consider" is very weak; it is possible to "consider" something, but then choose to disregard it entirely when setting the actual standards.

We recognize CMS' interest in providing states with flexibility in setting their network adequacy standards. However, without a minimum level below which standards may not fall, "flexibility" permits states to set standards that are far below what is appropriate. Therefore, Bi-State recommends that CMS significantly strengthen the NA protections by:

Bi-State Primary Care Association Comments

RE: Proposed Rule for Medicaid and CHIP Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; 80 Fed. Reg. 31098 (June 1, 2015)

July 27, 2015

Page 20

- Establishing minimum NA standards for each of the provider types listed in §438.68(b) – e.g., primary care, OB/GYN. These standards should address, at a minimum:
 - Number and types of providers relative to the number of patients;
 - Language and physical accessibility;
 - Travel time and distance;
 - Wait times for appointments; and
 - Accessible hours for working populations.

At the same time, recognizing the importance of giving states flexibility to adjust minimum standards to meet their unique situations, Bi-State recommends that that CMS:

- Give states the flexibility to establish different standards as long as:
 - The standards are at least as stringent as the CMS-established minimum standards; and
 - The state demonstrates that it has actively considered all factors outlined in §438.68(c).

Finally, we recommend that CMS:

- Require MCOs to contract with Essential Community Providers (ECPs¹⁵) according to same standards applied to Qualified Health Plans participating in Federally-Facilitated Marketplaces. (i.e., contract with at least 30% of all ECPs in the service area, at least one from each category in each county, etc.)

Adding this requirement would be consistent with two key goals of this regulation. First, it would further align the standards applied to Medicaid MCO and Marketplace plans, making it easier for MCOs to establish a single provider network that would meet the requirements of both programs. More importantly, it would help patients who churn between Medicaid, the Marketplace, and being uninsured to maintain a consistent care provider, regardless of their coverage status. When these individuals are uninsured, they frequently turn to ECPs (and particularly FQHCs, who treat all individuals regardless of ability to pay) for care. Due to the ECP contracting requirements for Marketplace QHPs, these individuals are often able to stay with their ECP when they join a Marketplace plan. By extending the ECP contracting requirements to Medicaid MCOs, CMS can provide further consistency for these individuals.

Also, as with the NA requirements, Bi-State recommends that states be given the flexibility to establish different standards for ECP contracting, as long as these standards are at least as stringent as the CMS-established minimum standards.

¹⁵ As defined in Section 1301(c)(1)(C) of the Affordable Care Act.

Bi-State Primary Care Association Comments

RE: Proposed Rule for Medicaid and CHIP Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; 80 Fed. Reg. 31098 (June 1, 2015)

July 27, 2015

Page 21

In closing, Bi-State recognizes that this NRPM represents many years of hard work on the part of dozens of CMS and HHS/OS officials, and we thank you for the opportunity to comment on it. Please do not hesitate to contact me at (603) 228-2830, extension 113 or via e-mail at kstoddard@bistatepca.org if you require clarification on the comments presented above.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kristine Stoddard', with a long horizontal flourish extending to the right.

Kristine E. Stoddard, Esq.
Director, New Hampshire Public Policy
Bi-State Primary Care Association

Bi-State Primary Care Association Comments

RE: Proposed Rule for Medicaid and CHIP Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; 80 Fed. Reg. 31098 (June 1, 2015)

July 27, 2015

Page 22

ATTACHMENT 1

Overview of Federally Qualified Health Centers

For 50 years, Health Centers have provided access to quality and affordable primary and preventive healthcare services to millions of uninsured and medically underserved people nationwide, regardless of their ability to pay. At present there are almost 1,300 health centers with more than 9,300 sites. Together, they serve over 22 million patients, including nearly seven million children and more than 1 in 7 Medicaid beneficiaries.

Health centers provide care to all individuals, regardless of their ability to pay. All health centers provide a full range of primary and preventive services, as well as services that enable patients to access health care appropriately (e.g., translation, health education, transportation.) A growing number of Health Centers also provide dental, behavioral health, pharmacy, and other important supplemental services.

To be approved by the Federal government as a Health Center, an organization must meet requirements outlined in Section 330 of the Public Health Service Act. These requirements include, but are not limited to:

- Serve a federally-designated medically underserved area or a medically underserved population. Some Health Centers serve an entire community, while other target specific populations, such as persons experiencing homelessness or migrant farmworkers.
- Offer services to all persons, regardless of the person's ability to pay.
- Charge no more than a nominal fee to patients whose incomes are at or below the Federal Poverty Level (FPL)
- Charge persons whose incomes are between 101% and 200% FPL based on a sliding fee scale
- Be governed by a board of directors, of whom a majority of members must be patients of the health center.

Most Section 330 Health Centers receive Federal grants from the Bureau of Primary Health Care (BPHC) within HRSA. BPHC's grants are intended to provide funds to assist health centers in covering the otherwise uncompensated costs of providing care to uninsured and underinsured indigent patients, as well as to maintain the health center's infrastructure. Patients who are not indigent or who have insurance, whether public or private, are expected to pay for the services rendered. In 2013, on average, the insurance status of Health Center patients is as follows:

- 41% are Medicaid recipients
- 35% are uninsured
- 14% are privately insured
- 8% are Medicare recipients

No two health centers are alike, but they all share one common purpose: to provide primary health care services that are coordinated, culturally and linguistically competent, and community-directed care to uninsured and medically underserved people.



FEB 22 2011

Dear Health Center Director:

As you are aware, the Bureau of Primary Health Care (BPHC) has been working with the Asociación de Salud Primaria de Puerto Rico (ASPPR), the HRSA Office of Regional Operations (ORO) and other Federal partners to monitor the implementation of Mi Salud.

The launch of Mi Salud has led to numerous changes in the system for providing care to underserved patients throughout the Commonwealth. As health centers determine how to respond to the new system, this letter outlines issues that should be considered to ensure that health centers remain in compliance with Section 330 requirements.

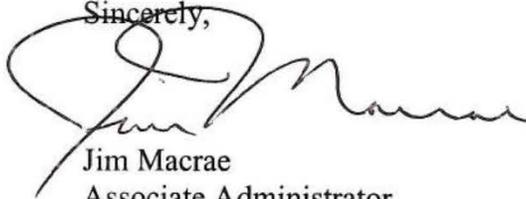
First, please be aware that Section 330 grant funds may only be used for services that are included under a grantee's approved scope of project. Therefore, if a health center is at financial risk for the costs of services beyond those covered under its scope, it must ensure that no Section 330 funds are used to offset the costs of these services. Since most health centers' approved scopes of project are limited to primary and preventive care, this means that Section 330 funds may not be used to offset the costs of specialty, hospitalization, and other types of care. Failure to comply with this requirement will result in a loss of Section 330 funding, as well as other benefits such as reimbursement from Medicaid and Medicare at FQHC rates and malpractice coverage under the Federal Torts Claims Act (FTCA).

Second, health centers should also be aware that the supplemental payments that the Puerto Rico Department of Health (PRDOH) is required to make are designed to cover the costs of the primary and preventive care services they provide. According to the Medicaid law, these payments must equal the difference between the health center's Prospective Payment System (PPS) rate and the amount it receives from a Managed Care Organization. Since the PPS rate reflects only the cost of required primary and preventive services, supplemental payments will cover costs for only these services, and not other types of services such as specialty and inpatient care. Therefore, receiving supplemental payments will not protect health centers from the financial risk associated with services beyond its required primary and preventive services.

For these reasons, all health centers operating in the Commonwealth should exercise due diligence in assuring that any contracts they sign will enable them to remain in compliance with all Section 330 requirements and ensure their long-term financial viability. Health centers are encouraged to collaborate closely with ASPPR, PRDOH and ASES to identify options for structuring contract arrangements.

Once again, we thank you for your continued service to the people most in need, and please let us know if our office can provide any technical assistance to help with these efforts.

Sincerely,

A handwritten signature in black ink, appearing to read "Jim Macrae". The signature is fluid and cursive, with a large initial "J" and "M".

Jim Macrae
Associate Administrator
Bureau Primary Health Care

- CC: Alicia Suárez, Directora, Asociación de Salud Primaria en Puerto Rico
- CC: Michael Melendez, Program Services Branch Manager, Division of Medicaid and Children's Health,
- CC: Nadia Gardana Cordero, Primary Care Office, Puerto Rico Department of Health