CHCANYS DEFINING NEW DIRECTIONS
Community Health Care Association of New York State www.chcanys.org

COMMUNITY HEALTH CENTER FQHC QUALITY

July 27, 2015

Submitted via www.regulations.gov

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

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:

The Community Health Care Association of New York State (CHCANYS) is pleased to respond to the 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).

As New York State's Primary Care Association, CHCANYS works closely with more than 60 federally qualified health centers (FQHCs) that operate over 600 sites across the state. FQHCs, also known as community health clinics, are non-profit, community run centers located in medically underserved areas that provide high-quality, cost effective primary care, include behavioral and oral health services, to anyone seeking care, regardless of their insurance status or ability to pay.

New York State's FQHCs serve 1.7 million New Yorkers annually. In 2013, 86% of patients served were below 200% of the poverty line and 52% received Medicaid. Compared to the rest of New York State, FQHC patients are twice as likely to receive Medicaid or be uninsured. One quarter of New York's FQHC patients are best served in a language other than English and three-fourths are racial and/or ethnic minorities. In short, FQHCs are New York's primary care safety net providers.

CHCANYS respectively submits the following comments on the Proposed Rule, which are consistent with those submitted by the National Association for Community Health Centers (NACHC.)

HIGHLIGHTED COMMENTS

The following comments on 340B and Medicaid managed care and Value Based Purchasing are aligned with those submitted by NACHC, but are of particular concern to CHCANYS:

1. **§438.3(s)(3) - Interaction of 340B and Medicaid managed care**

For many FQHCs in New York State, 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 MCO patients, as more than half of all FQHC patients in New York State are Medicaid beneficiaries, and of these, the vast majority 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 drugs[1].

Unfortunately, in the 5 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. For example, during the most recent budget process in New York, Governor Cuomo proposed that the State pay MCO participating 340B pharmacies at 340B Acquisition Cost plus a small fee consistent with the current 340B Fee-For-Service Medicaid requirements. The net result of this change would have been that the State would reap the 340B benefit and not the covered safety net provider. CHCANYS successfully advocated against this proposal and it was not enacted, but this experience demonstrates that language from CMS is sorely needed to clarify the role of the 340B program for safety net providers and prohibit the transfer of 340B benefits to a state or MCO.

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.*** CHCANYS 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.

[1] 42 USC §256b(a)(5)(A)(i).

§438.3(s)(3) Specifically, CHCANYS 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.**
- **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.**

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, CHCANYS offers the following comments on the interaction of the 340B and Medicaid Managed Care programs:

- **CHCANYS 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, CHCANYS 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 also should 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 BIN-PCNs for their Medicaid plans and to share these BIN-PCNs with 340B Covered Entities.** Bank Identification Numbers (BINs) and Processor Control Numbers (PCNs) 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 has 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 providers would contravene Congressional intent and frustrate the purpose of the 340B program.

2. §438.6(c) – Value-based purchasing

Under § 438.6(c), CMS proposes to allows 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."

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."[2] 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.[3] 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.

The timing of these proposed rules is particularly important in New York State, as our State is embarking on an ambitious statewide payment transformation program. As part of New York's Delivery System Reform Incentive Payment (DSRIP) Program, CMS recently approved the State's Value Based Payment Roadmap, in which New York commits that by year five of the five year DSRIP Program, 80-90% of all managed care payments to providers will use value-based payment (VBP) methodologies. CHCANYS has been meeting regularly with NYS DOH to discuss what this will look like for FQHCs, and is active in several State-led workgroups seeking to implement the VBP plan. However, while NYS DOH has repeatedly noted that there will not be a "one size fits all" approach for VBP contracting with MCOs, further guidance from CMS that recognizes and protects the unique FQHC model in the context of VBP is crucial to ensuring the ongoing success of FQHCs in New York State.

Given these unique funding and operational restrictions, CHCANYS 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 FQHCs to assume risk for services beyond primary and preventive care as a prerequisite for obtaining a managed care provider agreement."**
  - **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."**

§ 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.

[2] 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.
[2]

[3] *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.

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." CHCANYS 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, CHCANYS 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.

3. § 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.

CHCANYS 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). [4]

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

[4] 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.

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 centers, and other monitoring mechanisms.[5] 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, CHCANYS 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 MCE reimbursements promptly without being hobbled by delays occasioned by the MCE's clinician credentialing process.

For these reasons, CHCANYS 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,

[5] 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.

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.)

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, CHCANYS 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.**

ADDITIONAL COMMENTS

4. **Alignment with Other Health Coverage Programs**

Appeals and Grievances – CHCANYS supports CMS' proposals to align appeal and grievance procedures among Medicaid MCO, Marketplace and Medicare Advantage plans. Many of these proposals will increase beneficiary protections under Medicaid MCOs and will also reduce confusion among patients who 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

Medical Loss Ratio – CHCANYS generally supports CMS' proposal to establish minimum MLR 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.

5. Standard Contract Provisions

CHCANYS 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: CHCANYS 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: CHCANYS 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 Rx requiring prior authorization: CHCANYS 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.

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

CHCANYS 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.

7. 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 MCE 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.[6] Per §1902(bb)(5)(A).), these payments must be made "by the State," rather than by the MCO.

CHCANYS was recently the plaintiff in a lawsuit against New York State in which the Second Circuit Court of Appeals held that federal law dictates the State, not the MCO, is responsible for ensuring FQHCs are paid their full PPS rate.[7] A more complete discussion of the legal issues is included the comments NACHC submitted in response to these rules. CHCANYS support NACHC's recommendation that CMS clarify that the only FQHC-related costs that are appropriate for inclusion when calculating actuarially sound capitation rates 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

[6] 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.*

[7] "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).

network."[8] CHCANYS 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. Therefore, CHCANYS 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.**

8. Program Integrity

§ 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 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

[8] 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.

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.[9]

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, CHCANYS 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**
- **Require the State to recertify to the MCO and provider at regular intervals (for example, 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(for example, within three days following notification from the State). Establish a maximum length of time for which the**

[9] *See* 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.

State and MCO can suspend payments prior to making a final determination as to the credible allegation of fraud.

9. Beneficiary Protections

CHCANYS strongly supports CMS' numerous proposals to strengthen the beneficiary protections under managed care.

- **§438.54(c)(2) and (d)(2) – Strong support for "choice period" of at least 14 days**. CHCANYS 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.** CHCANYS 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.

10. Modernize Regulatory Requirements

<u>§438.68 – Network Adequacy Standards</u>

CHCANYS 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 CHCANYS 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, CHCANYS recommends that CMS significantly strengthen the NA protections 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.**

At the same time, recognizing the importance of giving states flexibility to adjust minimum standards to meet their unique situations, CHCANYS recommend 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 (ECPs[10]) 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 contacting 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, CHCANYS 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.

CHCANYS appreciates the opportunity to comment on this Proposed Rule.

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

Sincerely,

Beverly Grossman
Senior Policy Director