



July 27, 2015

**VIA ELECTRONIC SUBMISSION**

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

**Attention: CMS-2390-P  
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; Proposed Rules**

Dear Sir/Madam:

Thank you for the opportunity to comment on CMS-2390-P, "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; Proposed Rules" (hereinafter referred to as "the proposed rule").

The Center for Children and Families is based at Georgetown University's Health Policy Institute with the mission of improving access to health care coverage among the nation's children and families, particularly those with low and moderate incomes. As such, we have a long history of conducting analysis, research and advocacy on issues relating to delivery of services in public programs.

We are attaching detailed comments on the proposed rule, but also would like to highlight in this cover letter those issues that we believe it is most important to address in the final rule.

- 1. Transparency:** We applaud HHS for making transparency a priority in this update to the managed care regulations. States will be required to post or link to vital consumer information, including enrollee handbooks, provider directories and drug formulary lists. Additionally, key program information including network adequacy standards and quality data, which has often been difficult to obtain in the past, must be posted in accessible formats on state websites. We believe the rule can be further strengthened with respect to transparency by requiring that important contract information as detailed and referenced under §438.602 be posted where it can be

accessed quickly and with minimal cost, rather than allowing states the option to make such information upon request. Moreover, we believe that all consumer information should be posted together on a section of the state's website dedicated to consumer information.

Finally, we urge you to improve the reporting and transparency requirements at both the state and federal levels with respect to the proposed Medical Loss Ratio as outlined in our comments below. We strongly support the inclusion of an MLR for Medicaid and CHIP, but believe that much of its public policy value will be undermined if it is not readily available to the public. We believe that the rule can be strengthened in this area.

- 2. *Quality Assessment and Improvement:*** We strongly support the requirement for a comprehensive statewide quality strategy that encompasses all Medicaid and CHIP delivery systems, including fee-for-service. This expanded scope offers much promise in advancing state efforts to measure and improve the quality of care provided to children and adults enrolled in our public coverage programs. In particular, the proposed rules provide an opportunity for greater integration of the Child Core Set of Health Quality Measures and lessons learned from the Pediatric Quality Measures Program. We appreciate the requirement for a public engagement process as states developed their comprehensive statewide quality strategy, but urge HHS to strengthen the provision by specifying standards similar to those required under §1115 demonstrations.
- 3. *More Robust Consumer Information:*** We commend HHS for boosting requirements for consumer information, by specifying detailed content that must be posted or linked on state websites for potential enrollees, enrollees and the public. From establishing standardized definitions for common managed care terms to requiring that specific information be included in enrollee handbooks and provider directories to making public key quality data, the proposed rule will advance understanding of how managed care works and provide crucial information that consumers need to make an informed plan choice. To foster efficiency and consistency, we encourage HHS to develop model definitions and materials for states to adopt or adapt. Additionally, all written materials should be subject to consumer testing to promote comprehension and understanding.
- 4. *Enrollment Opportunity and Choice Counseling:*** All consumers should be allowed adequate time to review information and receive personalized assistance in selecting a managed care plan that best fits their needs. Research has shown that consumers are less likely to make an active choice if they are passively enrolled or auto-assigned to a managed care plan. Offering a specified period of coverage under fee for service and boosting access to information and consumer assistance are important strategies to encourage more beneficiaries to compare their options and make an informed choice, and in doing so, better understand how their managed care plan will work. However, the 14 days proposed in the rule is insufficient for consumers to wade through complex insurance information, and thus, we

recommend that the final rule provide a 30-day enrollment standard enrollment period, while allowing exempt populations 45 days to choose a plan.

5. **Disenrollment:** The proposed rule largely maintains current requirements that allow consumers to disenroll in the first 90 days for any reason, or at any time with cause. We believe that two additional circumstances justify cause – if an enrollee’s primary care provider leaves the network or if a provider from whom the enrollee is receiving ongoing care leaves the network – and urge HHS to adopt these reasons. Additionally, we believe that aligning the annual opportunity to switch plans with renewal is a logical time for consumers to re-evaluate plans and will minimize consumer confusion and dissatisfaction that results from the two processes not being aligned. Lastly, we believe using the term ‘disenrollment’ as it applies to their annual opportunity to change plans can be confusing to enrollees and may discourage them from selecting a new plan. We encourage HHS to consider other terminology such as “open enrollment period” or “annual opportunity to change plans.”
  
6. **Access:** We applaud HHS for its recognition that network adequacy is a foundational component of a health plan’s ability and capacity to provide services and for proposing standards for network adequacy. We also are pleased that HHS proposed that states ensure that enrollees have access to all services covered in a manner that meets state accessibility and affordability standards. We note a tension inherent in the proposed rule that may hinder efforts to regulate network adequacy in managed care plans. On the one hand, the proposed rule seeks to align network adequacy requirements with other coverage programs. At the same time, the proposed rule aims to maintain state flexibility. Aligning standards across coverage programs and maintaining state flexibility are both worthy goals, but can potentially work at cross-purposes. In light of these issues, we recommend that CMS maintain a degree of state flexibility while also establishing minimum, multi-faceted, quantitative standards for network adequacy, such as appointment wait times, provider-patient ratios for adult and pediatric primary and specialty care, and time and distance standards for primary and specialty care.

If you have questions regarding our comments, you may contact Tricia Brooks or me at (202) 687-3110.

Sincerely,



Joan Alker

## TABLE OF CONTENTS

<b>MEDICAID MANAGED CARE</b>	<b>5</b>
<i>A. General Provisions</i>	5
§438.2 Definitions	5
§438.3 Standard contract requirements	5
§438.4 Actuarial soundness	6
§438.6 Special contract provisions related to payment	7
§438.7 Rate certification submission	7
§438.8 Medical loss ratio standards	8
§438.9 Provisions that apply to non-emergency medical transportation PAHPs	10
§438.10 Information requirements	10
<i>B. State Responsibilities</i>	22
§438.52 Choice of MCOs, PIHPs, PAHPs, PCHHS, and PCCM entities	22
§438.54 Managed care enrollment	22
§438.56 Disenrollment: Requirements and limitations	24
§438.62 Continued services to enrollees	27
§438.66 State monitoring requirements	28
§438.68 Network adequacy standards	30
§438.71 Beneficiary support system	35
<i>C. Enrollee Rights and Protections</i>	38
§438.104 Marketing activities	38
<i>D. MCO, PIHP and PAHP Standards</i>	40
§438.206 Availability of services	40
§438.207 Assurances of adequate capacity and services	40
§438.208 Coordination and continuity of care	40
§438.210 Coverage and authorization of services	41
<i>E. Medicaid Quality</i>	42
§431.502 State comprehensive quality strategy	42
§431.504 State comprehensive quality strategy development, evaluation, and revision	44
§438.310 Basis, scope and applicability	46
§438.320 Definitions	46
§438.330 Quality assessment and performance improvement program	48
§438.332 State review and approval of MCOs, PIHPs, and PAHPs	50
§438.334 Medicaid managed care quality rating system	51
§438.340 Managed care elements of the state comprehensive quality strategy	53
§438.350 External quality review	53
§438.354 Qualifications of external quality review organizations	54
§438.356 State contract options for external quality review	55
§438.358 Activities related to external quality review	55
§438.360 Nonduplication of mandatory activities	57
§438.362 Exemption from external quality review	59
§438.364 External quality review results	60
§438.370 Federal Financial Participation	60
<i>F. Grievance System</i>	61
<i>G. Program Integrity</i>	62
§438.602 State Responsibilities	62
<b>CHIP REQUIREMENTS</b>	<b>62</b>
<i>A. General Provisions</i>	62

§457.1201 Standard contract requirements	62
§457.1203 Rate development standards	64
§457.1205 Medical loss ratio	65
§457.1206 Non-emergency medical transportation PAHPs	67
§457.1207 Information requirements	69
<i>B. State Responsibilities</i>	79
§457.1210 Managed care enrollment	79
§457.1216 Continued services to enrollees	79
State monitoring requirements	81
§457.1218 Network adequacy standards	83
Beneficiary support system	87
<i>C. Enrollee Rights and Protections</i>	92
§457.1224 Marketing activities	92
Additional enrollee rights and protections	93
<i>D. MCO, PIHP and PAHP Standards</i>	93
§457.1230 Access standards	93
§457.1233 Structure and operation standards	95
<i>E. CHIP Quality</i>	95
§457.760 CHIP component of the state comprehensive quality strategy	95
§457.1240 Quality measurement and improvement	100
§457.1250 External quality review	106
<i>F. Grievances and Program Integrity</i>	111
§457.1260 Grievances	111
Program integrity and program integrity safeguards	111

## MEDICAID MANAGED CARE

### A. General Provisions

#### §438.2 Definitions

We recommend that HHS add a definition of Limited English Proficiency (LEP). The term is used in §§438.10 and 438.420, but is not defined. Given that the Department of Health and Human Services (HHS) and the Department of Justice have articulated a definition, it should be used – and it would promote consistency to include it in this definitional section.

**Recommendation:** We recommend adding at §438.2: *LEP means Limited English Proficiency, as defined by the Office for Civil Rights' Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 68 Fed. Reg. 47311 (Aug. 8, 2003).*

#### §438.3 Standard contract requirements

We support HHS' decision to restructure the contract requirements currently set forth in §438.6 and separate the standard provisions unrelated to rate setting. We agree that this promotes readability and simplicity. We also support expanding inspection and audit rights in §438.3(g) and the requirement to submit audited financial reports.

We enthusiastically support HHS' decision to expand the anti-discrimination prohibition at §438.3(d)(4). In particular, we commend HHS for adding sex, sexual orientation, and gender identity as protected categories. These protections are crucial because discrimination on these bases creates barriers to accessing medically necessary care—either by discriminatory plan practices (e.g., in enrollment, covered and excluded services, medical necessity definitions, or utilization controls), provider refusals, or treatment avoidance due to perceived discrimination in treatment.

We also strongly support the decision to add disability as a protected category. As stated in the preamble, beneficiaries with disabilities are increasingly enrolled in managed care and the protections for these enrollees reflect the challenges they often face, including lack of accessible information and services, discrimination in enrollment, and difficulty navigating managed care generally. Adding disability as a protected category provides an important broad protection for beneficiaries with disabilities that will cover discriminatory actions that many not be specifically covered by other provisions but still have a strong adverse effect. This could include instances such as when enrollees with disabilities who have high service needs or are difficult to deal with are treated poorly by managed care entities in an effort to get such individuals to switch managed care entities. We believe these anti-discrimination protections should also apply at disenrollment.

**Recommendation:** Apply the anti-discrimination provisions at §438.3(d) to disenrollment in addition to enrollment.

We welcome the new reference to §1557 of the Affordable Care Act (ACA) at §438.3(f). It is clear that §1557 applies to Medicaid MCOs, PHPs, and all types of PCCMs; however, adding it to the regulations will help emphasize and publicize the new requirement.

#### **§438.4 Actuarial soundness**

We strongly agree that capitation rates for MCOs, PIHPs and PAHPs must be reviewed and approved by CMS as actuarially sound, and that approval be conditioned on meeting the requirements described in subparagraphs (b)(1-8).

We especially support the requirement in (b)(1) that proposed differences in capitation rates must not be based on the federal financial participation (FFP) percentage associated with the covered populations. We agree with the discussion in the preamble that such practices could lead to cost-shifting from states to the federal government, and that such differences would not be based on generally accepted actuarial principles or practices. We also support the requirement in (b)(8) that a medical loss ratio (MLR) of at least 85 percent be assumed in the capitation rate. We are concerned, however, that there is no upper limit on the MLRs assumed into capitation rates, and the only requirement is that the capitation

rates overall be adequate for necessary and reasonable administrative costs. This requirement is vague and could permit some capitation rates to be set at inadequate levels, which would be reflected with MLRs approaching 100 percent (with the likely result in beneficiaries experiencing limited access to needed care). We recommend that HHS specify an appropriate upper limit on the MLRs assumed in capitation rates.

#### **§438.6 Special contract provisions related to payment**

We support limiting the size of incentive payments that states can establish to no more than five percent of the capitation payments attributable to the enrollees or services covered by the incentive arrangement. Five percent appears to be a reasonable limit; it provides a financial incentive for achieving specified activities, targets, performance measures and quality-based outcomes without distorting behavior at the expense of fulfilling the primary goal of furnishing all Medicaid-covered services to enrollees. We are concerned that no similar numerical limitation applies to the size of withhold arrangements. While the determination of actuarial soundness would take into account how much of a withhold payment is reasonably achievable, that standard is too weak. The goal of any withhold arrangement should be to reduce payments to MCOs, PIHPs or PAHPs that fail to meet goals and measures that all plans are expected to meet (in contrast to providing additional payments in the form of incentive payments for meeting goals and measures that the State hopes all plans meet). Without any limits, withhold arrangements could unduly reduce rates and effectively make them actuarially unsound. Moreover, they could be improperly used to delay payments to MCOs, PIHPs and PAHPs, which could have a harmful impact on the provision of care to enrollees. To avoid this result, we recommend that a five percent limitation also be applied to withhold arrangements.

#### **§438.7 Rate certification submission**

We strongly support requiring states to submit to HHS for review and approval all MCO, PIHP and PAHP rate certifications concurrent with the review and approval process for contracts. We also support the requirement that states submit relevant data, trend factors, the non-benefit component of rates, and any adjustments as part of their rate certification submission, and that the states' actuary certify the final rates paid under each risk contract. We recommend that HHS clarify in the final rule that all such information should be publicly available to ensure transparency and public accountability.

In particular, we strongly support the requirement that states provide HHS information about the risk adjustment methodologies they are using in their Medicaid managed care programs, including the data, models, methods for calculating relative risk factors, and their predictive value. While many states use risk adjustment in some form in their Medicaid managed care contracts, comparative information about the risk adjustment methodologies used is not currently available. Having states submit this information to HHS, along with HHS making such information publicly available, would allow comparative analysis of risk adjustment across state Medicaid programs and an assessment of their relative effectiveness. That, in turn, could produce best practices for states to adopt to

better ensure that their rates appropriately take into account the relative risk of enrollees under each contract.

We also support the provision in subsection (d) that the state must provide any additional information upon CMS's request if CMS determines such information is relevant to the approval of the rate certification. This would ensure that CMS has all the information it needs to determine whether capitation rates are actuarially sound and fully comply with the requirements of this proposed rule.

#### **§438.8 Medical loss ratio standards**

We strongly support the proposed addition of a MLR as a contractual requirement for MCOs, PIHPs and PAHPs operating in Medicaid (and CHIP) beginning in 2017. This new requirement aligns Medicaid and CHIP with requirements established by the ACA for the private sector and requirements already established for Medicare Advantage plans. MLRs have the potential to ensure better value for public funds used to purchase coverage for Medicaid and CHIP beneficiaries. MLRs also enhance the ability of states to assess the actuarial soundness of capitation rates and ideally promote the success of better actors in the insurance market – *i.e.*, those with lower administrative costs who are devoting higher levels of premium funds to paying for incurred claims.

A recent study by researchers at the Urban Institute speaks to the public policy value of having an MLR. This analysis found that *“The ACA’s minimum MLR rule had a direct effect on insurer behavior that increased value for consumers and increased efficiency in the individual and small group markets.”*<sup>1</sup>

In order to maximize the potential value of an MLR in the Medicaid and CHIP programs, we offer the following specific comments:

**Recommendation:** *Delete language at 438.8 implying that the MLR is optional for states: We support the requirement for states to use the MLRs and MLR history for assessing actuarial soundness and setting payment rates under §438.4. We agree that there should be a uniform minimum MLR of at least 85 percent and urge you to delete language at 438.8(c) that begins “If a State elects to mandate a minimum MLR...” This language creates the impression that the minimum threshold of 85 percent for the MLR is optional and contradicts the intent of the regulation.*

**Recommendation:** *In order to align Medicaid’s MLR with the MLR in the private market, and in order to ensure that the full public policy value of an MLR is realized, we recommend that States collect remittances from each MCO, PIHP and PAHP that fails to meet the minimum MLR.*

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<sup>1</sup> Clemens-Cope et al, “Health Insurer Responses to Medical Loss Ratio Regulation: Increased Efficiency and Value to Consumers” Robert Wood Johnson Foundation, May 2015.



An enforceable MLR of 85 percent is a threshold that plans should not have difficulty meeting. According to the Kaiser Family Foundation, in the vast majority of States for which data were available, the average Medicaid managed care MLRs were 85 percent or higher. Moreover, as the preamble states, Milliman data state that the average Medicaid managed care MLR from 2011 to 2013 was 87 percent.

Given that the MLR is a new requirement for Medicaid, a phase-in may be appropriate. At a minimum, however, all States and MCOs, PIHPs and PAHPs should be subject to an annual minimum MLR requirement of 85 percent enforceable through remittances. There also may be a need to ensure that remittances do not have an adverse impact on particular types of MCOs such as safety-net plans. HHS should carefully evaluate, as it implements an annual enforceable MLR requirement, whether certain types of MCOs, PIHPs and PAHPs are more likely to experience unexpected year-to-year MLR fluctuations and if so, consider potential adjustments to take such fluctuations into account in its MLR requirement.

**Recommendation:** *Establish a uniform MLR reporting year.* We are concerned that allowing each State to set the MLR reporting year (which could be the contract year, calendar year, State fiscal year, or Federal fiscal year but must be consistent with the rating year), would make it impossible to make comparisons across States and particularly across plans offered by the same issuer but in different States. Again this flexibility would undermine one of the key values of an MLR, which stems from its use as a tool to drive improved decision-making in the pursuit of greater value by consumers and states.

**Recommendation:** *Strengthen public reporting and transparency provisions.* The value of an MLR is greatly diminished if it is not publicly reported and routinely audited. For consumers choosing plans, as well as for researchers, stakeholders and legislators, a publicly reported MLR that is consistently defined and reported by all plans in a timely way is an important step forward to driving better quality of care in the Medicaid program. We understand that CMS intends for MLRs to be reported in a timely way but we believe these requirements must be strengthened in the final rule. The current language in our judgment could result in states reporting the information to CMS but not necessarily to the public.

Specifically, we recommend amending §438.74(a) to include the following language: *State reporting requirement.* (1) The State must annually submit to CMS a summary description of the report(s), **and the reports themselves**, received from the MCO(s), PIHP(s), and PAHP(s) under contract with the State under § 438.8(k) with the actuarial certification described in §438.7. **The reports and summaries must also be made publically available by HHS, including by posting on an internet website.**

**Recommendation:** We recommend that HHS modify the regulation to require that the MLR requirements applying to a MCO, PIHP, and PAHP apply to the totality of care provided by that contractor, regardless of any subcontracts that are in effect or

entered into. In practice, this means that managed care plans should not be allowed to wholesale include the expenses paid to a subcontractor in the numerator, without adjusting that expense for the administrative costs of the subcontractor. If a contractor provides only services, it could all count in the numerator (incurred claims), however if a contractor only performs administrative functions, it should not count in the numerator. Meanwhile, if the contractor performs mixed functions (both services and administration), the plan should attribute to the MLR the respective portions of the contract for services and administration. For example, if a subcontractor is paid \$10 million to provide dental services, but that subcontractor itself operated at a 70% MLR, the managed care plan should include \$7 million (and not \$10 million) for the dental services in the numerator of the managed care plan's MLR calculation.

**Recommendation:** At §438.602 regarding state responsibilities, we recommend that subsection (g) on transparency be amended to require the state post on an internet website the summaries (but not the reports) that are submitted to HHS to comply with the above reporting requirement (i.e., delete the language for states to make this information available upon request). We also recommend that states be required to post on an internet website a comprehensive and easily accessible list of Medicaid and CHIP plans and their MLRs. *See comments on §438.602.*

#### **§438.9 Provisions that apply to non-emergency medical transportation PAHPs**

We support full alignment with the NEMT PAHP requirements in Medicaid and CHIP, as noted in our comments for §457.1206. To that end, we recommend adding a requirement to include audited financial reports at §438.9(b)(1), as is done in §457.1206(b)(1).

#### **§438.10 Information requirements**

Overall, we applaud the administration's effort to boost information requirements to assure that consumers receive all of the information they need to make informed plan selections and are able to access the assistance and services they need.

##### *§438.10(a) Definitions*

We believe the definition of "prevalent" should be clarified even further to ensure that the intent of standardizing the availability of written translations of non-English languages is clear. Additionally, we recommend that the requirement be based on an entity's service area rather than statewide or county data.

**Recommendation:** *Prevalent* means a non-English language determined to be spoken by a significant number or percentage of **1,000 or 5 percent of** potential enrollees or enrollees **in the entity's service area** that are limited English proficient and consistent with standards used by the Office for Civil Rights in enforcing anti-discrimination provisions **in Title VI of the Civil Rights Act of 1964 and Section 1557 of the Affordable Care Act. If a covered entity conducts targeted marketing,**

***outreach or other activities directed at a specific non-English language group, that covered entity must provide all materials specified in subsection (d)(3) in that language as well as other materials related to the type of marketing, outreach or other activities being conducted.***

We also support the recommendation of the National Health Law Program (NHeLP) to add a definition of competent healthcare interpreter, competent translation services, and competent healthcare translator.

*§438.10(b) Applicability*

We support aligning applicability across all types of managed care.

*§438.10(c) Basic rules*

We applaud the requirement to bring transparency to the forefront by requiring that a broad array of content as specified in this regulation be provided to enrollees and potential enrollees (§438.10(c)(3)). We agree that certain types of information are more useful for enrollees, potential enrollees or other stakeholders. However, the proposed rule at times distinguishes between enrollees and potential enrollees. This distinction should be for targeting information and outreach, not to limit whom has access to the information. Accordingly, we recommend that HHS strengthen and broaden the rule by requiring that the state website must make all information provided to enrollees and potential enrollees publicly available.

**Recommendation:** Amend §438.10(c)(3) as follows: The state must operate a website that provides ***to the general public*** the content specified in paragraphs ***(e) through (g)*** and (h) of this section, §438.68(e), ***§438.74***, §438.364(b)(2), and §438.602(g), either directly or by linking to individual MCO, PIHP, PAHP or PCCM entity websites. ***The state website should have a dedicated section for consumer information that includes all of the information that must be posted as detailed in Part 438.***

We believe that establishing standard definitions for managed care terminology will help enrollees and potential enrollees understand what services they are able to receive, the types of providers within their available network, and provide basic understanding of managed care as a whole (§438.10(c)(4)(ii)). Such an understanding will help enrollees make informed choices about their health care; however, allowing states to develop their own definitions for the terminology could present problems. States may develop definitions that are different from other types of healthcare plans, which could create confusion for enrollees who may be familiar with a certain term but understand it to mean something different than the state's definition.

Additionally, states could develop different definitions from one another. If someone enrolled in a managed care plan in Florida moves to Georgia, the varying definitions could cause confusion for this individual. State-developed definitions may also be confusing for enrollees, so they may not understand the services and benefits they are entitled to receive.

We also believe that it will be more cost-effective for states to adopt standard terms rather than duplicitous creation of such terms.

To promote health literacy and reduce state costs, we recommend that HHS develop the definitions for the required terminology with state and stakeholder input, so there will be standardization across all plans in every state. If HHS is unable to create standard definitions for managed care terminology, then HHS should develop model definitions for states to adopt or use as a starting point for developing their own definitions. Such standard definitions should be consumer-tested before they are finalized.

**Recommendation:** HHS should develop standard definitions for managed care terminology at §438.10(c)(4)(ii), or minimally develop model definitions through sub-regulatory guidance for states to use.

The NPRM requires that enrollee information provided electronically must meet accessibility and other standards for electronic information (§438.10(c)(6)). However, the regulatory language is confusing and could be construed as though providing information in this format is optional. HHS should require states to provide this information electronically, and in compliance with the standards in the rule. Additionally, while we support the requirement at §438.10(c)(6)(ii) to display the information in a prominent and readily accessible place, we believe this requirement can be strengthened by the language we have suggested above under §438.10(c)(3). Many state websites are difficult for consumers to navigate, with information moving to new places frequently. Therefore, we believe that states should be required to section specific to consumer information so that all such information is in one place.

**Recommendation:** HHS should amend §438.10(c)(6) to read: (6) **All** Enrollee information required in this section ~~may not~~ **must** be provided electronically by the State, MCO, PIHP, PAHP, PCCM or PCCM entity ~~unless,~~ **and must meet** all of the following:

It is unclear what the intended “mechanism” might be to help enrollees and potential enrollees (§438.10(c)(7)). A mechanism could take many forms, such as a Frequently Asked Question document (FAQ) or Fact Sheet, which will likely be insufficient in assisting enrollees and potential enrollees in understanding the requirements and benefits of the plan. Establishing a structure to help enrollees and potential enrollees understand the requirements and benefits of the plan is an essential way to ensure that enrollees are aware of available services. Considering the overall scheme §438.10, a structure is needed to make sure enrollees and potential enrollees are able to easily navigate their managed care plan and truly help individuals access their care.

To ensure that enrollees and potential enrollees receive the help they need, we recommend that HHS replace “mechanism” with “system.” To make sure that plans are providing the assistance described in this section, a mechanism is unlikely to provide the same help that a full-scale system would provide, and such a system is necessary to actually help enrollees and potential enrollees understand their plan. To further the goal of increasing information

access, we also recommend that HHS issue additional guidance to provide plans with a better understanding of what type of system is needed, even if the term mechanism is used. This will help managed care plans develop a structure that provides the necessary support to achieve the desired goals.

**Recommendation:** Amend §438.10(c)(7) as follows: Each MCO, PIHP, PAHP, and PCCM entity must have in place a ~~mechanism~~ **system** to help enrollees and potential enrollees understand the requirements and benefits of the plan. HHS should issue additional guidance to plans on system requirements.

#### *§438.10(d) Language and Format*

We generally support the requirements in subsection (d) with certain modifications and clarifications.

Paragraph (1) could be interpreted to leave the methodology for determining prevalent up to the state.

**Recommendation:** Amend subsection §438.10(d) as follows: (1) ~~Establish~~ *Utilize* the methodology for identifying the prevalent non-English languages spoken by enrollees and potential enrollees throughout the State, and in each MCO, PIHP, PAHP, or PCCM entity service area **developed under subsection (a)**.

Paragraph (2) implies that oral interpretation only has to be provided in prevalent languages, which is inconsistent with other parts of this section (e.g., paragraph (5)). We do not think this is the intent and, therefore, recommend rewording this paragraph. We also suggest that HHS require a minimum number of taglines be included on notices, and align with requirements in other coverage programs. Specifically, 45 CFR §155.205, known as the payment and parameters rule, requires private insurers to include taglines in at least 15 languages.

**Recommendation:** Amend subsection §438.10(d) as follows: (2) Make available **competent** oral **information in all languages and** written information in each prevalent non-English language. All written materials for potential enrollees must include **prominent** taglines in each prevalent non-English language **at least 15 non-English languages** as well as large print explaining the availability of written translation ~~or~~ **and** oral interpretation...

Paragraph (3) lists a number of “vital” documents to which this subsection applies, but does not specifically include denial and termination notices.

**Recommendation:** Amend subsection (d) as follows: (3) Require each MCO, PIHP, PAHP, and PCCM entity to make its written materials, including at a minimum, provider directories, member handbooks, appeal and grievance notices, **denial and termination notices**, and other notices that are critical to obtaining services...

There is widespread misunderstanding about the required knowledge, skills and abilities needed to be a competent healthcare interpreter, which can lead to a lack of competency in practice. It is important to maintain consistency in terminology, therefore we suggest changing “skilled interpreter” to “competent interpreter.” We also suggest defining “competent” interpreter. As a reference, the NHeLP and the National Council on Interpreting in Health Care and the American Translators Association, [\*What’s in a Word? A Guide to Understanding Interpreting and Translation in Health Care\*](#). The Guide explains the differences between interpreting and translation and the knowledge, skills and abilities needed of both. This can serve as a reference for states and managed care entities seeking to comply with requirements to provide competent and accurate interpreting and translation.

**Recommendation:** Amend subsection §438.10(d) as follows: (4) Make **competent** interpretation services available to each potential enrollee and require such MCO, PIHP, PAHP and PCCM entity to make those services available free of charge to each enrollee. This includes oral interpretation and the use of auxiliary aids such as TTY/TDY and American Sign Language. Oral interpretation requirements apply to all non-English languages and not just those identified as prevalent.

We support the inclusion of definitions relating to competent interpretation recommended by the NHeLP. We also recognize that other sections and subsections of the NPRM address language access and support the integration of “competent” interpretation services as recommended by disability and legal experts in other parts of this regulation. At §438.10(d)(6), we recommend adding a clarification to subparagraph (ii) that cross-references back to the requirement for a large print tagline. While we recognize (ii) is a more general requirement, we do not want any possibility of confusion with regard to the requirements for a large print tagline on all documents.

**Recommendation:** Amend §438.10(d)(6)(ii) as follows: Use a font size no smaller than 12 point, **except as required in subparagraph (d)(3)(i)**.

#### *438.10(e) Information for potential enrollees*

Providing potential enrollees with information about their benefits and services before choosing to enroll in a managed care program will enable these individuals to make an informed decision about their healthcare plan. When individuals are given more information about healthcare options, they will be better able to make the choice best for them.

#### *438.10(f) Information for all enrollees*

As noted previously, we believe all information should be available to all potential enrollees, enrollees and the public. However, §438.10(f)(3) requires that managed care entities only make information about physician incentive programs available upon request. Transparency is important for enrollees to fully understand their managed care and physician choices. To assist enrollees in understanding the care they receive, we recommend managed care plans must always provide information regarding physician incentive plans, regardless of whether an enrollee requests this information.

**Recommendation:** The state should post physician incentive programs on its website (§438.10(c)(3)) or require managed care plans to make such information available to potential enrollees, enrollees and the public without requiring that the information be requested.

We also recommend that the regulations include a requirement that plans inform enrollees that they can request that communications containing medical information be communicated to the enrollee at a specific mail or email address or telephone number, as designated by that enrollee. Allowing alternate and specifically designated contact information is important for a variety of enrollees. For example, enrollees who may receive certain services they do not want their parents knowing about (e.g., family planning services or supplies) and other enrollees who might be seeking "sensitive" services (e.g., victims of intimate partner violence, etc.).

**Recommendation:** Amend subsection (f) to add new paragraph (4): *The State and the MCO, PIHP, PAHP and, when appropriate, the PCCM entity must notify all enrollees of their right to designate a mail or an email address or telephone number to receive plan communications regarding medical information if the enrollee does not want the information being sent to the primary address designated on the application. Notice to the enrollee must clearly explain how the enrollee can make a request and provide a form or telephone number to call to complete the request.*

*§438.10(g) Information for enrollees of MCOs, PIHPs, PAHPs and PCCM entities – Enrollee handbook*

Enrollees need information about how to access services quickly after they enroll. Accordingly, we recommend defining "within a reasonable time" during which a managed care entity must provide each enrollee with an enrollee handbook at §438.10(g)(1).

**Recommendation:** Amend subsection §438.10(g) as follows: (1) Each MCO, PIHP, PAHP and PCCM entity must provide each enrollee an enrollee handbook, within a ~~reasonable time~~ **5 days** after receiving notice of the beneficiary's enrollment, which serves a similar function as the summary of benefits and coverage described in 45 CFR §147.200(a).

We believe that consumers will benefit from standardization of enrollee handbook formats and content for many of the same reasons cited in our recommendation for standard managed care terms at §438.10(c)(4)(ii). Accordingly, we urge HHS to develop model or template member handbooks. This will ensure uniformity across managed care plans within the state and across the country. If HHS cannot create models for states to use, a basic template will also help to create more uniformity and less confusion. To ensure that these informational materials are easy to understand and achieve the desired goal of informing enrollees, state or HHS materials should be subject to consumer testing. We also believe that model or template handbooks will save the time and expense of duplicating this effort across 50 states.

**Recommendation:** HHS should develop model or template enrollee handbooks.

At §438.10(g)(2)(xi), which contains grievance, appeal and fair hearing procedures and timeframes, we recommend including information about the availability of language services and accommodations. Most of the discussion of information requirements applies to plan activities and while grievances and appeals may be internal, to the extent that they may be delegated to a third party, and particular in the case of fair hearings which would be conducted by an entity external to the MCO entity, requirements for language services and accommodations for individuals with disabilities should be specified.

**Recommendation:** Amend §438.10(g)(2)(xi) to add a new (F) as follows: ***The availability of free, competent oral interpretation and written translation of materials for individuals who are limited English proficient and free auxiliary aids and services for individuals with disabilities.***

We appreciate the inclusion of information about how to access auxiliary aids and services at §438.10(g)(2)(xiii). We suggest similar language to inform about accessing language services so that the managed care entity must not only provide language services but also inform enrollees about their availability. We recommend amending subparagraph (xiii), but HHS could also insert a new subparagraph specifically about language services.

**Recommendation:** Amend subparagraph (xiii) of §438.10(g)(2) as follows: How to access auxiliary aids and services ***and oral translation and written materials***, including additional information in alternative formats or languages.

Given that the enrollee handbook is an excellent resource to aid enrollees in understanding their benefits and how to most effectively use a managed care program, we recommend requiring additional content at §438.10(g)(2) as follows:

The right to disenroll. Ensuring that enrollees understand their rights is essential to creating a streamlined and efficient healthcare delivery system, and we are appreciative of the increased requirements governing information for enrollees about their rights. For those currently enrolled, we recommend adding information to the enrollee handbook regarding the enrollee's right to disenroll. This information should be provided in addition to the notification the state provides. The enrollee handbook must also provide this information consistent with state requirements, where the plan must explain the disenrollment process and identify available alternatives. If the State limits disenrollment to a certain time frame, the enrollee handbook should specify that timeframe. This inclusion will inform enrollees that they have the right to leave the plan and evaluate their additional healthcare options.

**Recommendation:** Require that the enrollee handbook provide information regarding the enrollee's right to disenroll. This information should meet the same state requirements by providing information about the disenrollment process, healthcare alternatives, and timeframe restrictions.



Family planning services. Freedom of choice for family planning providers, which ensures that women may choose a provider that best suits their needs, is protected in the Medicaid statute. We are therefore concerned that the regulatory language requires plans to explain “the extent to which” enrollees can obtain family planning services out-of-network. In order to ensure that managed care plans do not misinform women about their ability to go out-of-network for family planning, or attempt to limit a woman’s family planning provider options, HHS should clarify that plans must fully inform women about these rights.

**Recommendation:** The enrollee handbook should clearly state there are no limits on a woman’s freedom of choice for family planning providers.

Network adequacy standards. Given that HHS has proposed that states set network adequacy standards based on time and distance, which is something that consumers can readily understand, we recommend that these standards be a required element of the enrollee handbook. Doing so provides another opportunity for states to validate that plans are meeting the standards.

**Recommendation:** The enrollee handbook should include the state’s network adequacy standards and what steps enrollees should take when they are not able to access services in a manner consistent with the standards.

Consumer testing. As healthcare terminology is confusing to many people, we recommend that the entire enrollee handbook be subject to consumer testing. The enrollee handbook is a resource for enrollees to understand how to effectively use their managed care program. To make certain the handbook serves this function, consumer testing is necessary to ensure enrollees are able to understand the information provided to them in the handbook.

**Recommendation:** The enrollee handbook should be subject to consumer testing to ensure enrollees understand the content of the handbook.

At §438.10(g)(3), it is not clear how the requirements of paragraph (g)(3) interact with paragraph (c)(6). Paragraph (c)(6) outlines when information may be provided electronically. However, subparagraphs (g)(3)(ii) and (iii) do not refer back to (c)(6).

**Recommendation:** Amend subsection (g)(3)(ii) and (iii) as follows:  
(ii) Provides the information by email, ***in compliance with subsection (c)(6)***, after obtaining the enrollee’s agreement to receive the information by email;  
(iii) Posts the information on the website of the MCO, PIHP, PAHP, or PCCM entity, ***in compliance with subsection (c)(6)***, and advises the enrollee that the information is available on the Internet, ***how to request a paper copy***, and includes the applicable Internet address...

Additionally, with regard to subparagraph (g)(3)(iii), we strongly support the requirement for plans that wish to provide information solely on its website to be required to provide notice of the available information to the enrollee in paper or electronic form. Many low-

income consumers may not have ready access to a computer. Further, individuals who are LEP may not have the ability to understand this information. We also suggest that if the entity wishes to advise the enrollee in electronic form, it must first obtain the enrollee's consent, similar to subparagraph (g)(3)(ii).

*§438.10(h) Information for all enrollees of MCOs, PIHPS, PAHPs and PCCM entities: Provider Directory*

We greatly appreciate the inclusion of a provider's cultural and linguistic capabilities in the provider directory. However, we are concerned about the self-identification of a provider's (or his/her staff's) language. Some providers may have some proficiency but are not completely bilingual, particularly when it comes to specialized healthcare terminology. They may be able to greet a person who is LEP in his or her language but not have sufficient language skills to take a health history or provide healthcare services in that language. Thus, a provider who is not sufficiently bilingual to provide services directly in a non-English language should not be included in a provider directory regarding language skills.

We recommend clarifying that for a provider's linguistic skills to be included in a provider directory, the provider must have demonstrated language proficiency in English (for non-native English speakers) and the non-English language, including specialized terminology, which can be demonstrated by taking a language proficiency examination. As a note, we reference "sign language interpreter" below rather than "American Sign Language" in recognition that some enrollees may need assistance in another country's sign language.

**Recommendation:** Amend §438.10(h)(1)(vii) as follows: The provider's cultural and linguistic skills, including languages spoken by the provider or by skilled medical interpreter at the provider's office. ***To include a provider's language skills in the directory, the provider must demonstrate he/she:***

***(A) Is proficient and able to communicate all healthcare information accurately in the non-English language or sign language for which the provider will provide services in a non-English language or sign language; and***

***(B) Possesses proficiency in the non-English language or sign language for which services will be provided including knowledge of:***

***(1) Specialized healthcare terms and concepts in both languages; and***

***(2) Any particularized vocabulary and phraseology likely to be used by the limited English proficient person or person needing a sign language interpreter, such as regional usages of terms;***

***If a provider only has conversational capabilities in a non-English language or sign language, the provider may not list that language in the provider directory.***

We appreciate inclusion of the term “skilled medical interpreter” as a method of identifying providers who can offer language services in their offices. However, as noted above, we would recommend changing “skilled” to “competent.”

Given the overall lack of understanding of the knowledge, skills and abilities required of healthcare interpreters throughout the healthcare arena, we recommend defining what a competent interpreter is so that if a provider identifies as having a “competent interpreter,” enrollees will be able to rely on that identification and not select a provider who really does not provide sufficient language services.

As compared to the above section about including language skills in a provider directory and using the broad term “sign language,” in our recommendations below we specifically reference “American Sign Language” since that is the only available certification for interpreters working with individuals who are deaf or hard of hearing.

**Recommendation:** In subsection (h)(vii), change “skilled” to “competent”. If a definition of “competent medical interpreter” is not added to subsection (a), add a definition as follows to clarify subsection (h)(1)(vii): ***A competent medical interpreter for a non-English language is either:***

***(A) An individual who has been certified by a national certifying body as a healthcare interpreter; or***

***(B) An individual who:***

***(1) Is over the age of eighteen;***

***(2) Is proficient and able to communicate information accurately in both English and in the language for which interpreting is needed;***

***(3) Possesses, to the extent necessary for communication, knowledge in English and in the language for which interpreting is needed of:***

***(i) Specialized healthcare terms and concepts; and***

***(ii) Any particularized vocabulary and phraseology used by the limited English proficient person or healthcare provider, such as regional usages of terms;***

***(4) Attests to comply with the National Code of Ethics and National Standards of Practice as published by the National Council on Interpreting in Health Care;***

***(5) Attests to adhere to the role of an interpreter as defined by the National Code of Ethics and National Standards of Practice as published by the National Council on Interpreting in Health Care; and***

***(6) Attests to adhere to HIPAA requirements to the same extent as the healthcare provider for whom interpreting is provided.***

***A competent medical interpreter for American Sign Language is an individual who has been certified by a national or state certifying body as an interpreter for American Sign Language.***

We are also concerned about the quality of translation of written materials. We believe covered entities must take appropriate steps to ensure that required translations are competent and not done through machine translation which does not produce competent translations.

We appreciate the recognition that the accessibility of a provider is important information to be included in the provider directory. While we support the features listed of the offices, exam room(s), and equipment, we are concerned that this section does not provide enough information about important aspects of accessibility for individuals with disabilities. As indicated in the proposed regulations, there are different aspects of physical accessibility that are important, including the provider offices and the available equipment. The minimum requirements for physical accessibility are set forth in the Americans with Disabilities Act Standards for Accessible Design and the related regulations. Accessible medical diagnostic equipment standards are being developed pursuant to the ACA's recognition of the issue in amending Section 510 of the Rehabilitation Act. Based on the presumption that providers are supposed to already be meeting the minimum standards of accessibility, the information that would be valuable in the provider directory is whether or not the provider is more accessible than minimally required in these clear guidelines. We also suggest that providers be provided an opportunity to indicate how they exceed the guidelines, such as in physical structure or equipment, or the types of disabilities they are specifically designed to accommodate. We are also recommending changing "office" to "office building" because a provider's office may be accessible but not be in a building or have an pathway that is accessible. We believe the term office may be too limiting and that the term office building is sufficiently broad to address this issue.

Further, we are concerned that the proposed regulation only addresses physical disabilities. People with disabilities experience barriers to healthcare that are often not about physical access, but about failures to accommodate for other types of disabilities. We believe that a provider directory should provide information about access generally so as to not discriminate amongst different types of disabilities in the information it provides. While there are not structurally measurable standards for non-physical disabilities, the provider directory should allow a provider to indicate other areas in which they have enhanced accessibility or commonly provide certain accommodations, such as sedation dentistry often used for people with intellectual disabilities or mental health diagnoses, or on-site American Sign Language interpretation.

**Recommendation:** Amend section (h)(viii) as follows: Whether the provider's office/facility ~~is accessible for people with physical disabilities~~ **exceeds physical accessibility requirements**, including offices **buildings**, exam room(s), and

equipment, **and/or the provider has other enhanced features for people with disabilities.**

*§438.10(i) Information for all enrollees of MCOs, PIHPs, PAHPs and PCCM entities: Formulary*  
We strongly support HHS' proposal to increase formulary transparency so that consumers can select the Medicaid managed care plan that best meets their individual health care needs. We agree that requiring plans to submit formulary information in a machine-readable format will facilitate search tools that allow potential enrollees and others to search across plans. Given the frequent changes in plan formularies, we urge HHS to specify how often plans must update formulary information. Additionally, it is important that formularies be available to potential enrollees in addition to enrollees.

**Recommendation:** Amend §438.10(i) as follows: Information for all **potential enrollees and** enrollees of MCOs, PIHPs, PAHPs and PCCM entities: Formulary. Each MCO, PIHP, PAHP, and when appropriate, PCCM entity, must make available in electronic or paper form, the following information about its formulary:

**Recommendation:** Add a new paragraph (4) to §438.10(i) setting standards for updating the formulary as follows: (4) Information included in a paper formulary must be updated at least monthly and electronic formularies must be updated no later than 3 business days after the MCO, PIHP, PAHP or PCCM entity revises the formulary.

With respect to §438.10(i)(2), we recognize that the practice of prescription drug tiering, including specialty drug tiers, is provided for in the Medicare Part D prescription drug benefit, and is common practice for private health plans including Qualified Health Plans (QHPs) available through the Marketplaces. However, formulary tiering by cost in Medicaid is quite limited. Federal law allows only two cost sharing levels based on income and only two tiers for prescription drugs – preferred and non-preferred. Moreover, the list distinguishing preferred and non-preferred drugs is determined by the state and would have to be consistently applied across all managed care plans in the state. *See* 42 C.F.R. §447.51. A Medicaid enrollee's income determines the applicable level of cost sharing, with some populations and services exempt.

Conceivably, Medicaid managed care plans could develop other types of prescription drug tiering, such as subjecting certain tiers to utilization management. Therefore, we recommend that HHS require plans to provide formulary information on prior authorization and other utilization management criteria, if applicable, to facilitate plan selection.

In addition we urge HHS to make an exceptions process *easily accessible*, and ensure that plans send adequate notice and explanation to beneficiaries regarding access to non-preferred medications at preferred drug cost-sharing, as well as emergency access to medication, and information on preferred and non-preferred medications. Finally, HHS should ensure that any such tiering structures comply with the rules regarding coverage

and authorization of services at §438.210 and must be explained to enrollees and potential enrollees.

**Recommendation:** Revise §438.10(i)(2) by adding subparagraphs (i)-(v) as follows: (2) What tier each medication is on. *MCOs, PIHPs, PAHPs, and, when appropriate, PCCM entities, shall:*

- (i) present prescription drug cost-sharing reflecting tiering by income and by preferred/non-preferred drugs as described in 42 C.F.R. §447.53;*
- (ii) provide information on prior authorization requirements or other utilization management criteria, if applicable;*
- (iii) make the exceptions process required under 42 C.F.R. §483.3(s)(7) easily accessible;*
- (iv) provide information on emergency prescription drug coverage and the availability of a 72 hour supply required under 42 C.F.R. §483.3(s)(6) and section 1927(d)(5) of the Act; and*
- (v) provide adequate notice and explanation to beneficiaries regarding access to non-preferred medications at preferred drug cost-sharing.*

## **B. State Responsibilities**

### **§438.52 Choice of MCOs, PIHPs, PAHPs, PCHHS, and PCCM entities**

We support the proposed changes to §438.52 that update this rule.

### **§438.54 Managed care enrollment**

We strongly support HHS' proposal to ensure that default enrollment into a managed care plan takes into account existing provider relationships in not only mandatory managed care programs, but also in states with voluntary programs that use passive enrollment processes. To strengthen this rule, HHS should also make clear that the plan must seek to preserve as many existing provider-enrollee relationships as possible when a Medicaid enrollee has more than one existing provider relationship.

**Recommendations:** We recommend amending §438.54(c)(6) and (d)(6) as follows:

§438.52(c)(6): A passive enrollment process must seek to preserve existing provider-beneficiary relationships and relationships with providers that have traditionally served Medicaid beneficiaries. *If the recipient has more than one existing provider of Medicaid services, the process should seek to preserve existing relationships to the greatest extent possible.*

§438.54(d)(6): The process must seek to preserve existing provider-beneficiary relationships and relationships with providers that have traditionally served Medicaid beneficiaries. *If the recipient has more than one existing provider of*

***Medicaid services, the process should seek to preserve existing relationships to the greatest extent possible.***

We support the adoption of enrollment standards in voluntary managed care and the alignment of standards for both voluntary and mandatory managed care. Managed care enrollees have faced barriers when attempting to enroll in or disenroll from managed care plans, or when seeking an exemption from mandatory managed care. However, because managed care is inherently complex and many enrollees have low health insurance literacy, we believe that the 14-day enrollment is insufficient for potential enrollees to research their options and make an informed plan selection. We also believe that three days is insufficient time for enrollees to receive and open a mailing. Additionally, we urge HHS to require states to include enrollment and disenrollment forms in the informational packets.

**Recommendation:** Amend §438.54(c)(2) as follows: (2) A State must provide ***exempt populations at least 45 calendar days and all other*** potential enrollees at least ~~14~~**30** calendar days of FFS coverage to provide the potential enrollee the opportunity to actively elect to receive covered services through the managed care or FFS delivery system. If the potential enrollee elects to receive covered services through the managed care delivery system, the potential enrollee must then also select a MCO, PIHP, PAHP, PCCM, or PCCM entity.

**Recommendation:** Amend §438.54(c)(3)(ii) as follows: (ii) Have a postmark or electronic date stamp that is at least ~~3~~**5** calendar days prior to the first day of the election period identified in paragraph (c)(2) of this section.

**Recommendation:** Add a new paragraph (4) to §438.54(c) as follows: (4) Enrollment and disenrollment forms.

(i) The State agency shall make an enrollment/disenrollment form available in information notices mailed to beneficiaries, at the enrollment presentations, by posting on a website that is accessible to the public, and at agency approved sites. The State agency or MCO, PIHP, PAHP, or PCCM shall mail the enrollment/disenrollment form to a recipient within 3 working days of receiving a telephone or written request for a form.

(ii) Plans shall make an enrollment/disenrollment form available at member services departments, by posting on a website that is accessible to the public, and shall mail the form to a recipient within 3 working days of receiving a telephone or written request for a form.

**Recommendation:** Amend §438.54(d)(2) as follows: (2) A State must provide ***exempt populations at least 45 calendar days and all other*** potential enrollees at least ~~14~~**30** calendar days of FFS coverage to provide the potential enrollee the opportunity to actively elect to receive covered services through the managed care or FFS delivery system. If the potential enrollee elects to receive covered services

through the managed care delivery system, the potential enrollee must then also select a MCO, PIHP, PAHP, PCCM, or PCCM entity.

**Recommendation:** Amend §438.54(d)(3)(ii) as follows: (ii) Have a postmark or electronic date stamp that is at least ~~3~~**5** calendar days prior to the first day of the election period identified in paragraph (c)(2) of this section.

**Recommendation:** Add a new subsection §438.54(d)(4) as follows: (4) Enrollment and disenrollment forms.

(i) The State agency shall make an enrollment/disenrollment form available in information notices mailed to beneficiaries, at the enrollment presentations, by posting on a website that is accessible to the public, and at agency approved sites. The State agency or MCO, PIHP, PAHP, or PCCM shall mail the enrollment/disenrollment form to a recipient within three working days of receiving a telephone or written request for a form.

(ii) Plans shall make an enrollment/disenrollment form available at member services departments, by posting on a website that is accessible to the public, and shall mail the form to a recipient within three working days of receiving a telephone or written request for a form.

#### **§438.56 Disenrollment: Requirements and limitations**

##### *§438.56(b) Disenrollment requested by the MCO, PIHP, PAHP, PCCM or PCCM entity*

We believe the provision protecting enrollees from a managed care entity request for disenrollment because of an adverse change in the person's health status or utilization of services can be strengthened. We also applaud HHS for proposing in §438.3(d) rules prohibiting enrollment discrimination and recommend that the same protections explicitly apply to disenrollment. *See §438.3(d) comments.*

**Recommendation:** We recommend that HHS amend §438.56(b) by:

Amending paragraph (2) as follows: Provide that the MCO, PIHP, PAHP, PCCM or PCCM entity may not request disenrollment because of an adverse change in the enrollee's health status, or because of the enrollee's **medical or mental health condition**, utilization of medical services, diminished mental capacity, or uncooperative or disruptive behavior resulting from his or her special needs (except when his or her continued enrollment in the MCO, PIHP, PAHP, PCCM or PCCM entity seriously impairs the entity's ability to furnish services to either this particular enrollee or other enrollees).

Adding a new paragraph (3) that reads as follows: **(3) Provide that the MCO, PIHP, PAHP, PCCM or PCCM may not request disenrollment because of an enrollee's race, color, language, national origin, disability, age, sex, gender identity, or sexual orientation.**



*§438.56(c) Disenrollment requested by the enrollee*

We suggest that HHS clarify §438.56(c) to make clear that the 12-month period before an enrollee is offered an opportunity to switch plans or disenroll starts upon enrollment into the Medicaid managed care plan, not at the end of the initial 90-day period.

Annual disenrollment is an important time for enrollees to evaluate their plan selection and determine whether their plan is meeting their specific needs. However, consumers often overlook this time of year because it is often confused with renewal. We have heard from several states that consumers are frequently confused between these two, often distinct, periods of time. We recommend that states align these two processes so open enrollment and renewals occur during the same period of time. This will allow consumers to complete their annual renewal and make any changes in plans at the same time, instead of in silos. Open enrollment aligned with renewal has been instituted by several states including Minnesota, Oregon and Indiana. Other states that have open enrollment at a separate time than renewals have seen several problems. For example, Illinois reports a high number of enrollees failing to complete their renewals and subsequently being dropped from the program. Many advocates report that enrollees mistakenly believe they renewed following their open enrollment period. Alignment of Medicaid managed care processes would reduce confusion, align processes, and more closely mirror processes in place in the health insurance marketplaces.

**Recommendation:** Amend § 438.56(c)(ii) as follows: At least once every 12 months thereafter following the *beneficiary's initial enrollment into a MCO, PIHP, PAHP, PCCM or PCCM entity, and coinciding with the individuals annual renewal period.*

*§438.56(d) Request for disenrollment*

Given that HHS is limiting the opportunity to disenroll to the initial 90-day enrollment period, we believe that it is important to include additional good causes for disenrollment at any time. Specifically, we recommend that a consumer be able to disenroll if their primary care provider is no longer in the network or if the provider from whom an enrollee has been receiving ongoing treatment or services leaves the plan network, resulting in disruption in care.

**Recommendation:** We recommend amending §438.56(d)(2) by adding the following good cause reasons for disenrollment at any time:

*(vi) The enrollee's primary care provider leaves the plan's network.*

*(vii) A provider from whom an enrollee has been receiving ongoing treatment or services leaves the plan network, resulting in disruption in care.*

*§438.56(e) Timeframe for disenrollment determinations*

There are often delays in processing requests for disenrollment, including expedited disenrollment requests, which can significantly harm enrollees. We accordingly support HHS' proposal to clarify the timeframes for states to process enrollee requests for disenrollment. Such rules will help ensure that enrollees' requests are acted upon in a

timely manner. In addition to the clarification that HHS proposes, we urge HHS to also specify how and by when the managed care entity must notify enrollees whether their disenrollment request, including expedited disenrollment requests, was approved or denied.

**Recommendation:** Specify the method and timing for managed care entities to notify enrollees whether their request for disenrollment was approved or denied.

*§438.56(f) Notice and appeals*

In paragraph (f)(1), the regulation specifies that states must provide enrollees notification of disenrollment rights at least 60 days prior to the start of each enrollment period if the enrollee is locked into the plan. We recommend instituting new terminology for the period of time in which an enrollee is allowed to switch managed care health plans. In most states, this period is called ‘open enrollment’ rather than ‘disenrollment.’ The word ‘disenrollment’ could imply that enrollees are fully disenrolling from Medicaid altogether and are not re-enrolling into a health plan. This word could cause confusion among beneficiaries rather than recognition of the opportunity to switch plans. ‘Annual open enrollment’ is the more common terminology used in insurance and will create a clear, consistent message to enrollees that aligns with Medicare and QHPs. If there are concerns about using the same term that applies to the annual open enrollment period in the Marketplaces, the term ‘annual opportunity to switch plans’ might be an alternative. We would recommend doing consumer testing to determine the best terminology.

**Recommendation:** Use the term ‘annual open enrollment’ or ‘annual opportunity to switch plans’ to describe the annual disenrollment opportunity for consumers.

Additionally, we support adding regulations to the Notice and Appeals subsection §438.56(f) that requires states to send information about the availability and existence of managed care plans along with written notices of disenrollment rights if the enrollee is still determined eligible for Medicaid. This requirement will provide enrollees with information that will inform them of their choices to select another health plan. It will also provide an excellent opportunity for outreach and education especially if the choice of managed care plans has changed. Packaging plan information with disenrollment notices will streamline processes and clearly indicate next available steps at the time of disenrollment.

**Recommendation:** Insert a new paragraph (2) at §438.56(f). ***(2) Provide that enrollees receive health plan information with their written notice of disenrollment rights at the start of each enrollment period.***

It is important for enrollees to receive timely notice when their disenrollment is processed. Accordingly, we recommend adding a new state action under the notice and appeals section at §438.56(f)(2) (and renumbering (2) to (4)). We propose that states be required to send a written communication to the beneficiary confirming the disenrollment once it has been processed by the state. Providing this information to consumers will provide additional clarity and security to the system. These notifications should be provided through the mail or through electronic communications, depending on individual consumer

preferences (as proposed in §438.10). We recommend that the notices include information about what steps to take in the event that the information is wrong as well as where consumers can go if they need assistance.

**Recommendation:** Insert a new paragraph (3) at §438.56(f). ***(3) Provide written disenrollment confirmations to beneficiaries with the effective date of disenrollment within 5 days of processing the disenrollment.*** Renumber the proposed paragraph (2) to (4).

#### **§438.62 Continued services to enrollees**

We commend HHS for expanding this section to add specific requirements aimed at ensuring that Medicaid beneficiaries have access to services during times of transition. We strongly support HHS' goal of maintaining existing provider relationships during times of transition, and we agree that these protections are needed for all enrollees, not just those in rural areas as currently provided for in §438.62.

We are concerned, however, that the proposed regulatory language in subsection (b)(1) will not fully achieve HHS' goal of ensuring continuity of care for enrollees during times of transition. In particular, we are concerned that the proposed language will only ensure continuity of care with an existing provider when a person moves "from FFS to a MCO, PIHP, PAHP, PCCM or PCCM entity or transition from one MCO, PIHP, PAHP, PCCM or PCCM entity to another." We believe there are other times of transition when a person may need to continue care with an existing provider that should be addressed by these regulations, including moves into a MCO, PIHP, PAHP, PCCM or PCCM entity from another insurance affordability program or private insurance; from an MCO, PIHP, PAHP, PCCM or PCCM entity to FFS; and when a provider leaves the enrollee's MCO, PIHP, PAHP, PCCM or PCCM entity.

In addition, we are extremely concerned that the proposed language defining the circumstances when an enrollee is eligible for continuity of care is too narrow. The proposed language would only permit enrollees to continue seeing an existing provider when lack of continuity would cause enrollee to "suffer serious detriment to their health or be at risk of hospitalization or institutionalization." We are concerned that this language would force enrollees to change providers in many situations that would not necessarily rise to the level of a serious health detriment or risk of hospitalization, but where continuity of care is enormously important to avoid unnecessary gaps in treatment or to ensure that an enrollee has appropriate access to time-sensitive services. We urge HHS to amend the criteria for when a state must require plans to offer continued access to out-of-network providers, as described below.

**Recommendation:** Amend §438.62(b) as follows: The state must have in effect a transition of care policy to ensure continued access to services during a transition from FFS to a MCO, PIHP, PAHP, PCCM, or PCCM entity ~~or~~; ***transition into a MCO, PIHP, PAHP, PCCM or PCCM entity from another insurance affordability program or private***

***insurance; transition from an MCO, PIHP, PAHP, PCCM or PCCM entity to FFS; and when a provider leaves the enrollee's MCO, PIHP, PAHP, PCCM or PCCM entity. The transition of care policy must provide for continued access to services when an enrollee, in the absence of continued services, would suffer serious detriment to their health or be at risk of hospitalization or institutionalization is completing a course of treatment, has a scheduled procedure within 60 days of the transition, is receiving care for a terminal illness, is receiving pregnancy or post-partum care, or the state determines that other circumstances warrant continued access.***

We commend HHS for setting forth the criteria states must consider in developing a plan to avoid disruptions in care during times of transition. We appreciate that HHS will require states to ensure that the scope of services is not reduced during a transition, and that HHS will require states to ensure that enrollees can continue to see their current providers for a period of time during a transition.

We suggest that HHS amend this section to add specific language to ensure that consumers are not subjected to additional prior authorization criteria or barriers to care when they experience transitions. Too often, consumers must repeat prior authorization for a drug or assessment for a treatment that has already been approved by FFS or their prior plan when they transition, which creates delays to care. We believe HHS' intent is that consumers should not face these kinds of barriers to care during transitions and we therefore suggest specific language to avoid confusion. In addition, we recommend that HHS set a minimum period of time for which consumers may have continued access to their current providers. At a minimum, enrollees who are engaged in a course of treatment or who have a scheduled procedure should be allowed to see their current provider until the treatment or procedure and any necessary follow-up are complete. Enrollees who are pregnant or post-partum should be allowed to complete their prenatal and post-partum care with their current provider. Enrollees who are being treated for a terminal illness should be permitted to see their current providers for the duration of the illness.

**Recommendation:** Amend §438.62(b)(1)(i) as follows: The enrollee has access to services consistent with the access they previously had, ***including access to currently authorized treatments without additional assessment, prior authorization, or utilization management requirements***, and is permitted to retain their current provider for ~~a period of time~~ ***the duration of their course of treatment or scheduled procedure including any necessary follow-up appointments, or—in the case of a pregnant or post-partum enrollee—until 60 days post-partum, or—in the case of an enrollee with a terminal illness—for the duration of the illness, or—in the case that the state identifies other circumstances that warrant continued access—for a period of time identified by the state***, if that provider is not in the MCO, PIHP or PAHP network.

#### **§438.66 State monitoring requirements**

We commend HHS for clarifying, consolidating, and expanding state monitoring

requirements and requiring states to use data collected to improve the performance of its managed care program. While a number of these requirements are found in the current regulations, such as monitoring grievances and appeals, some states have done a poor job in conducting monitoring activities and using the information collected. Moreover, the lack of federal monitoring of state compliance has resulted in managed care programs that fail to meet the needs of enrollees.

The proposed regulation requires states to have a “system” for monitoring key areas. However, as explained below, we urge HHS to impose more specific requirements and guidelines on the state monitoring system. These include transparency and reporting requirements, mandatory reporting of data, performance, and monitoring activities, and robust stakeholder consultation and engagement.

State monitoring activities should coordinate with the state and managed care Drug Utilization Review, inform the development of the state quality strategy, and provide a formal role for the Medical Care Advisory Committee and the state and LTSS stakeholder groups. State monitoring should also include audits and performance reviews conducted outside the EQR process, such as investigations and reports issued by state inspectors general, auditors, comptrollers, and other entities. Thus, we urge HHS to recognize the indispensable role of such independent monitoring – not only for managed care plans, but state agencies as well.

We strongly support the inclusion of a requirement for data collection pursuant to state monitoring requirements to improve performance of the managed care program. The current monitoring and reporting requirements result in the provision of fragmented program information by states, impeding oversight efforts. However, the proposed regulation contains no transparency requirement for the data collected, and no opportunity for consumers and community stakeholders to evaluate the data. Therefore, we urge HHS to require states to report on their monitoring activities and share data collected with the MCAC and the state LTSS stakeholder groups on, at minimum, a quarterly basis. We also urge HHS to require states to monitor the adequacy of the prescription drug formularies offered to Medicaid managed care enrollees, including use of the exceptions process allowing enrollee access to non-formulary drugs and for off-label uses.

The proposed rule requires states to monitor provider network management. (§438.66(b)(10)). We agree that monitoring provider networks is essential for ensuring that enrollees have actual access to providers and services. Therefore, we urge HHS to clarify that monitoring provider network management includes monitoring adherence to network adequacy standards required under §438.68, timely access standards required under §438.206(c)(1) and provider directories under §438.10(h). Moreover, HHS should specify that monitoring must include direct testing for compliance with network adequacy and timely access standards. State monitoring and direct testing should be in addition to EQR validation of network adequacy standards.

According to the HHS Office of the Inspector General (OIG), direct testing of provider networks is the most effective means of evaluating adherence with network adequacy

standards.<sup>2</sup> As the OIG noted, fluctuating and inadequate provider networks, as well as inaccurate provider directories, significantly impede timely access to services. By requiring ongoing state monitoring of provider directories, network adequacy and timely access standards in addition to EQR validation, HHS can strengthen oversight and help ensure enrollees can actually access providers and services.

In addition, we urge HHS to clarify the requirements governing medical management committees described in proposed §483.66(c)(7). We agree that any committee reports and minutes should be considered as part of performance improvement activities and should be publicly available. However, the duties, membership, and authorities of these committees are unclear and are not defined elsewhere in the regulation. Any medical management committee operated by the state, MCO, PAHP, PHIP, or PCCM entity should be subject to transparency requirements including open meetings and stakeholder participation.

**Recommendation:** Amend §438.66(c) as follows: The State *must report on its monitoring activities under subsection (b) and provide the data collected to the Medical Care Advisory Committee established under §431.12 of this chapter or an advisory committee with similar membership, and the stakeholder consultation group specified in §438.70, at minimum, on a quarterly basis. The State* must use data collected from its monitoring activities to improve the performance of its managed care program, including at a minimum:

Amend subparagraph (10) as follows: Provider network management, *including direct testing of provider directories, network adequacy, and timely access standards required under §§438.10(h), 438.68, and 438.206(c)(1).*

Add new subparagraphs as follows: *(13) Data collected by DUR activities conducted by the state, MCO, PAHP, PHIP, or PCCM entity including, but not limited to overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications. (14) Monitor the adequacy of the MCO, PAHP, PHIP, or PCCM entity (if applicable) prescription drug formulary, including data on enrollee education and utilization of the exceptions process required under §438.3(s)(7) for non-formulary and off-label drug uses.*

#### **§438.68 Network adequacy standards**

We support the goal of the proposed rule to establish a framework for regulating and ensuring access to providers in Medicaid managed care. This is particularly important as more than two-thirds of children in Medicaid and CHIP receive their coverage through

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<sup>2</sup> See HHS Office of the Inspector General (“OIG”), [State Standards for Access to Care in Medicaid Managed Care](#) (Sept. 2014), and OIG, [Access to Care: Provider Availability in Medicaid Managed Care](#) (Dec. 2014).

managed care arrangements.<sup>3</sup> We concur with HHS that the adequacy of a managed care plan's network ought to be a primary component of any assessment of a state's managed care program.

In this context, we laud many aspects of the proposed rule's efforts to ensure that enrollees in managed care plans have access to needed services, and we identify these areas of agreement below. However, we also suggest a central tension inherent in the proposed rule that may hinder efforts to regulate network adequacy in managed care plans. On the one hand, the proposed rule seeks to align network adequacy requirements with other coverage programs, particularly Medicare Advantage Plans and QHPs sold through the Marketplace. At the same time, the proposed rule aims to maintain state flexibility. Aligning standards across coverage programs and maintaining state flexibility are both worthy goals, but can potentially work at cross-purposes. In light of these issues, we recommend that CMS maintain a degree of state flexibility while also establishing minimum, multi-faceted, quantitative standards for network adequacy, such as appointment wait times, provider-patient ratios for adult and pediatric primary and specialty care, and time and distance standards for primary care and adult specialty care. We strongly caution against the sole use of time and distance for pediatric specialty care. The lack of access to a pediatric specialty facility resulting from the sole use of a distance standard for network adequacy could delay services for very sick children or compel them to seek care in settings ill-equipped to address their pediatric service needs.

#### *§438.68(a) General rule*

We support the proposed rule's requirement articulated in §438.68(a) that a state that contracts with a managed care organization must develop network adequacy standards. However, we are concerned that the proposed rule's efforts to maintain state flexibility will result in an overly fragmented system that will undercut the goal of aligning standards across coverage programs and may not effectively ensure that those enrolled in Medicaid managed care plans have adequate access to care across all states. The proposed rule requires that states set minimum time and distance standards while also proposing additional metrics that states might adopt to ensure access to care. There are a variety of ways in which states might exercise flexibility in regulating their managed care markets.

#### *§438.68(b) Provider-specific network adequacy standards*

Establish national quantitative standards to ensure access. We recommend that HHS go further than requiring states to set time and distance standards for network adequacy and urge the final rule to also create a national floor for state standards in this regard. We propose the following serve as a floor for such standards: that a provider is available within 30 minutes or 15 miles of the residences or workplaces of 90 percent of enrollees for primary care (adult and pediatric), behavioral health (adult and pediatric), pediatric dental providers, hospitals, pediatric tertiary care and pharmacies, and that specialist providers (adult and pediatric) and birth centers are available within 60 minutes or 30 miles of the

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<sup>3</sup> S. Burwell, "2014 Annual Report on the Quality of Care for Children in Medicaid and CHIP," United States Department of Health and Human Services (November 2014), available at <http://www.medicaid.gov/medicaid-chip-program-information/by-topics/quality-of-care/downloads/2014-child-sec-rept.pdf>.

residences or workplaces of 90 percent of enrollees. Establishing such standards would ensure a minimum level of access for beneficiaries while providing states with the ability to implement their own higher standards for time and distance or other metrics as they see fit.

**Recommendation:** Set a national floor for time and distance standards at §438.68(b).

However, we urge that the final rule also require that in setting their own specific standards for time and distance, states take into account whether a majority of enrollees use public transportation in calculating travel times. Doing so will help ensure that these standards are designed with the needs of the population that Medicaid serves in mind. Along these lines, the final rule might also require that states establish quantitative standards regarding provider hours and availability.

**Recommendation:** Take into account that many Medicaid beneficiaries rely on public transportation when calculating travel times. Consider including quantitative standards regarding provider hours and availability.

We also support establishing a floor for standards regarding appointment wait times. Such a standard is especially important for the population that Medicaid serves that may face difficulty in taking time off of work or arranging for child care in order to make it to a medical appointment. Since a long wait time at a provider's office could disrupt such arrangements, we propose that for any routine, preventive, or non-urgent appointments, the in-office waiting time should not exceed 30 minutes from the time of the scheduled appointment.

**Recommendation:** Establish maximum appointment wait time standards.

Given the importance of primary care providers for all enrollees but especially children, we recommend that the final rule also include national standards regarding provider-patient ratios for adult and pediatric primary care, at one adult primary care provider for each 1200 adult enrollees and one pediatric primary care provider for each 1000 enrollees under 21.

**Recommendation:** Establish a national standard for primary care provider to patient ratios.

We also suggest that the final rule more specifically delineate a managed care plan's obligations to ensure that enrollees with specialized needs receive care. Given the regionalized nature of specialty care, especially specialty pediatric care, we urge HHS to include in the final rule a requirement that plans arrange for care to be provided by a geographically-proximate out-of-network provider or provide transportation for an enrollee to travel to an in-network provider that is located beyond the maximum time and distance. HHS should also actively monitor how plans provide out of network care.



**Recommendation:** Require managed care plans to provide out-of-network care or transportation to in-network care outside the maximum time and distance standards for enrollees with specialized needs.

In addition, we urge HHS to require that managed care organizations include in their provider directories information on network tiering of physicians as well as any changes in cost sharing and out of pocket charges that enrollees may encounter when using out of network providers. *See comments on §438.10(h).*

**Recommendation:** Monitor provision of out-of-network care and ensure up-to-date information is provided to enrollees in their provider directories.

Consider unique needs of specific populations. We also support the proposed rule's stipulation at §438.68(b) of specific network provider types for which such standards must be established, including both adult and pediatric primary care, OB/GYN, behavioral health, adult and pediatric specialist care, hospitals, pharmacies, and pediatric dental. The health care needs of children and adolescents differ from those of adults in many respects, and therefore we strongly support the inclusion of pediatric-specific standards and recommend that HHS consider the full range of required types of pediatric providers for whom network adequacy standards should be developed so children's full scope of health care needs are appropriately addressed.

In this regard, we concur with HHS that states specifically include pediatric primary, specialty, and dental providers but also urge HHS to include a requirement that states establish standards for pediatric behavioral health providers. With regard to behavioral health specifically, we urge HHS to prohibit any behavioral health carve-outs in the final rule, and that any requirement regarding access also apply equally to behavioral health. If behavioral health carve-outs cannot be prohibited, we urge HHS to require direct access to specialty care providers as needed.

**Recommendation:** Consider the full range of pediatric providers for whom particular network adequacy standards should be developed. Establish time and distance standards for pediatric behavioral health providers. Prohibit behavioral health carve-outs, or alternatively, require plans to allow direct access to specialty care providers as needed.

With respect to the importance of recognize the distinction between pediatric and adult care, we urge the final rule to require managed care organizations to document how children with chronic conditions move from pediatric to adult providers as they "age out" of pediatric care.

**Recommendation:** Monitor the transition from pediatric to adult providers as children with chronic conditions "age out" of pediatrics.

*§438.68(c) Development of network adequacy standards*

We also strongly endorse the proposed rule's inclusion of a requirement that states consider the availability of network providers to communicate with LEP enrollees in their preferred language when the state is developing time and distance access standards.

**Recommendation:** Maintain the requirement at §438.68(c)(1)(vii) and (viii) to consider access for LEP enrollees and individuals with disabilities.

*§438.68(e) Publication of network adequacy standards*

Promote monitoring and transparency. In addition to establishing important requirements to ensure access, the proposed rule's provisions regarding network adequacy would also enhance transparency, both in general and with regard to specific categories of enrollees. We support the proposed requirement from §438.68(e) that states publish their network adequacy standards, though we encourage the final rule to go further and require that these state-level standards in turn be published via a federal platform such as Healthcare.gov or Medicaid.gov, given that these sites serve as points of access and sources of information for many Medicaid enrollees. We also support requiring states to publish their network adequacy standards and make these standards available, at no cost to individuals with disabilities in alternate formats. Along these lines, we appreciate that §438.207 requires states to provide documentation underlying their certification of Medicaid plan networks to HHS, and request that the final rule also require states to make the information that they collect during the monitoring process available to the public. Similarly, we urge that any efforts that states may take to monitor network adequacy (for example, enrollee or provider surveys, audits of appointment requests and encounter data, and 'secret shopper' studies) are also made available to the public.

**Recommendation:** Require states to publish network adequacy standards on a federal platform. Make the documentation underlying Medicaid plan network certification and state monitoring efforts public.

More generally, we encourage HHS to include in the final rule mechanisms to monitor the impact of the network adequacy requirements on specific populations, especially children. This will help states to make adjustments to their standards as needed should specific metrics not ensure enrollee access to providers as intended. We also urge HHS to monitor any material changes to the composition of a plan's provider network, such as a change in the size or demographic characteristics of the enrolled population or the termination of a provider contract. We believe that requiring states to actively monitor and publically release information on how plans are complying with network adequacy requirements and how these rules affect enrolled populations will produce information that can be utilized by enrollees, regulators, and other stakeholders to improve access to care for children and families in Medicaid. This monitoring requirement can also serve as a useful enforcement tool.

**Recommendation:** Monitor the impact of network adequacy requirements on specific populations, especially children. Monitor material changes to the composition of a plan's provider network. Make the data underlying such monitoring and the results of such monitoring publicly available.

## §438.71 Beneficiary support system

### *§438.71(a) General Requirement*

Medicaid managed care has proven to be a difficult system to navigate for consumers, and enrollees often encounter problems related to enrollment and disenrollment, service denials, enrollee rights, and provider network limitations. We often hear beneficiaries report frustrations in accessing services, understanding their rights and how to enforce them, and the lack of assistance when they encounter problems. Therefore, we strongly support the creation of a mandatory beneficiary support system (BSS) to help beneficiaries choose the most appropriate managed care entity to meet their needs; provide assistance and education in understanding managed care, including enrollee rights and mechanisms for advocacy; and provide assistance in navigating the grievance and appeal process. Knowledgeable professionals must perform these activities in a conflict-free manner that is accessible and meaningful for that individual and/or the individual's caregivers. As much as we support having a BSS, we are concerned that as written, the BSS will not provide the services needed by all enrollees. We therefore urge that the BSS requirements be revised to ensure that it will truly meet the needs of enrollees in Medicaid managed care, especially as it continues to evolve and become more complex.

At §438.71(a), we suggest adding a reference to caregivers and to move the requirement from §438.71(e)(3)(i) with respect to representation in order to ensure equal access to representation regardless of whether the beneficiary is using LTSS.

**Recommendation:** Revise §438.71(a) to add a reference to caregivers; eliminate the distinction between the services for beneficiaries and those in or seeking LTSS with respect to representation:

(a) General requirement. The State must develop and implement a beneficiary support system that provides support to beneficiaries *and/or caregivers* both prior to and after enrollment in a MCO, PIHP, PAHP, PCCM or PCCM entity.

***(1) An entity that receives non-Medicaid funding to represent beneficiaries at hearings, may, subject to approval by HHS, establish firewalls to provide choice counseling as an independent function.***

***(2) [Reserved]***

### *§438.71(b) Elements of the support system*

A core function of the BSS is to conduct outreach, which is important but insufficient. Enrollees and potential enrollees should have access to education and training on par with those received by managed care entities or providers. Accordingly, we recommend clarifying that all current and potential beneficiaries be included in §438.71(b)(1)(iii). Although training is listed as a minimum function of the proposed system, this training is only for MCOs, PHIPs, PAHPs, PCCMs, PCCM entities, and network providers. While we understand the proposed training is intended for the benefit of beneficiaries, it does not directly support them. In our experience, there is dearth of training for beneficiaries such

that very few understand their rights or how to self-advocate in managed care. As described below, we believe that the proposed requirements in §438.71(e) should not be limited to beneficiaries who use LTSS; therefore we have incorporated those requirements into subsection (b).

**Recommendation:** Amend §438.71(b) as follows: Elements of the support system.

- (1) A State beneficiary support system must, ~~include~~ at a minimum:
  - (i) ***Provide*** ~~€~~choice counseling for all beneficiaries;
  - (ii) ***Provide*** training for network providers as specified in paragraph (d) of this section;
  - (iii) Assistance for ***all*** enrollees ***and potential enrollees*** in understanding managed care;
  - (iv) ***Perform outreach to beneficiaries and/or caregivers;***
  - (v) ***Provide education on enrollees' grievance and appeal rights within the MCO, PIHP or PAHP; the State fair hearing process; enrollee rights and responsibilities; and additional resources outside of the MCO, PIHP or PAHP;***
  - (vii) ***Assist, upon request, in navigating the grievance and appeal process within the MCO, PIHP or PAHP, as well as appealing adverse benefit determinations by the MCO, PIHP, or PAHP to a State fair hearing. The system may not provide representation to the enrollee at a State fair hearing but may refer enrollees to sources of legal representation; and***
  - (viii) ***Be accessible in multiple ways including phone, internet, in-person, and via auxiliary aides and services when requested.***
  
- (2) The beneficiary support system must: ***provide review and oversight of system program data to provide guidance to the State Medicaid Agency on identification, remediation and resolution of systemic issues.***
  - (i) ~~perform outreach to beneficiaries and/or authorized representatives and~~
  - (ii) ~~be accessible in multiple ways including phone, Internet, in-person, and via auxiliary aids and services when requested.~~

*§438.71(e) Functions specific to LTSS activities*

We further recommend that the BSS include education for all enrollees in navigating the grievance and appeals process, not just LTSS beneficiaries. Specifically, the education and navigation assistance functions set forth in paragraphs (e)(2) and (e)(3) should not be limited to LTSS beneficiaries, but be included as minimum functions of the BSS generally. While we agree that it may be more likely that LTSS beneficiaries need additional assistance, there are non-LTSS beneficiaries who have similar needs in navigating the managed care system. For instance, there are many people with disabilities who do not receive LTSS but likely encounter similar or more severe difficulties in accessing care through managed care. In addition, other populations, such as those seeking services that are carved-out or women encountering refusals for reproductive health services who may need to go out of network, may need assistance in understanding their rights and

responsibilities as well as possibly navigating the grievances and appeals process. Therefore, this would have an added benefit of ensuring that the state would be better informed about how managed care is functioning for beneficiaries if the provisions of (e)(4) regarding identification of systemic issues to the state was for managed care generally, and not just LTSS.

We recommend clarifying §438.71(e)(1) to more fully explain how this proposed access point for complaints and concerns would function and what the relationship would be to the grievance and appeals process of subpart F. It is not clear whether the BSS would direct the person to the managed care entity's grievance and appeal process or whether HHS is proposing a separate complaint process that would be managed by the BSS. In either case, we are concerned about the high likelihood of confusion for beneficiaries regarding how they should complain about issues regarding their managed care entity and what their expectation should be about complaining through different processes.

We believe there are specific purposes in filing a grievance with the managed care plan through the process set forth in subpart F, including providing a chance to resolve the issue and ensuring that the grievance is recorded and part of the records reviewed by the state as part of its ongoing monitoring. Plans already have an incentive to address beneficiary complaints such that they do not become official grievances in order to convey the impression to the state that enrollees are satisfied with the plan even when they are not. If there is an alternate mechanism for complaint, plans could have an even greater incentive to redirect complaining beneficiaries to the BSS system if it is not effective.

We propose that the role of the BSS regarding resolving beneficiary issues with plans be to educate the beneficiary about their rights related to the issue, inform them how to file a grievance or appeal with the managed care entity, provide assistance where necessary, and track the subject of the complaint and the entity involved for reporting to the state about trends and systemic issues. We further believe that when a grievance is not resolved to the satisfaction of the beneficiary that fact should be reportable to the BSS by the beneficiary. Reporting such a complaint to the BSS would give the BSS and the state information about enrollee satisfaction and the function of a managed care entity's grievance system, and would give the beneficiary an opportunity to take the subject of the grievance outside of the closed system of the managed care entity. The BSS's role in grievances would not be to resolve them for the beneficiary, but to include them in the report on systemic problems. However, as part of navigating this part of the system, the BSS could provide information to the beneficiary about the relevant rights involved in the grievance to help the beneficiary better understand the response.

We also agree that an entity that receives non-Medicaid funding to represent beneficiaries at hearings, should, subject to approval by HHS, be able to provide choice counseling as an independent function (§438.71(e)(3)(i)). We firmly support extending the ability of non-Medicaid funded entities that represent beneficiaries at hearings, including protection and advocacy organizations and others that are federally-funded, to be allowed to contract with the Medicaid agency to provide choice counseling with appropriate firewalls. In our experience, protection and advocacy organizations are well versed in providing accessible

information and education about managed care options and processes. The same is true of legal services organizations with experience in representing Medicaid beneficiaries. We also suggest that states be allowed to contract with such entities for all BSS functions as many already do similar work.

**Recommendation:** Strike §438.71(e) and instead incorporate these provisions, with greater specificity regarding the role of the BSS in the grievance and appeals processes, as shown in the recommendation for §438.71(b), above.

#### *§438.71(c) Choice Counseling*

We appreciate that the BSS would have to meet the independence and freedom from conflict of interest standards if an individual or entity provides choice counseling on the state's behalf (§438.71(c)(2)). A BSS should be as independent from the state as possible to ensure effective support and advocacy for beneficiaries and a lack of conflict of interest in relation to the managed care entities. Entities that already have adversarial relationships, even if only from appeals, clearly do not have an interest in the managed care entity or the state's relationship with such an entity. If this proposed system is supposed to truly help beneficiaries and support them in understanding and effectively navigating the system, the BSS should be sufficiently apart from the state or the managed care entities. As shown with the history of the protection and advocacy systems in which many have moved from state-based divisions to independent entities, there is value in having an entity that supports beneficiaries be separate from the state. Based on the experience of some states that have similar programs, there is also value in separating choice counseling, which may be more associated with the state, and the other functions of a BSS.

We note that states should be encouraged to contract with existing entities that provide consumer assistance in enrolling in health plans, including navigator and SHIP entities. We also believe that federally-qualified health centers (FQHCs) serve an important function as enrollment counselors operating with funding from the Health Research and Services Agency and are bound to serve the best interests of consumers as detailed in 42 CFR 155.225. We encourage HHS to consider options that would allow FQHCs to serve as choice counselors. Finally, we believe that the BSS may also serve a useful role in helping beneficiaries renew their Medicaid enrollment, and HHS should consider adding renewal assistance as a BSS function.

### **C. Enrollee Rights and Protections**

#### **§438.104 Marketing activities**

We strongly support the continuance of restrictions on marketing activities in that the NPRM carries forward all of the prior provisions in §438.104.

We support the inclusion of PCCM entity as a type of entity to which the marketing provisions apply but note that it was inadvertently excluded in the definition of '*Marketing materials*' under §438.104(a)(2).

We support the inclusion of text messages and emails as types of activities that are considered cold-call marketing at §438.104(b)(1)(v).

After some consideration, we find it difficult to support HHS' decision to exclude QHPs in the definition of 'private insurance' at §438.104(a)(2). We understand that this provision is intended to level the playing field for QHPs and non-QHPs, since HHS and states have no authority over the conduct of non-QHPs. However, excluding QHPs from the marketing provisions means that they do not have to abide by any of the safeguards afforded beneficiaries in this provision and yet have enrollment information that allows them to target current enrollees. We recommend deleting this exclusion. Additionally, we recommend codifying guidance provided in a January 16, 2015 Frequently Asked Questions, regarding the role managed care plans may play to assist in state efforts to renew beneficiaries.

**Recommendation:** Amend §438.104(a) by striking the last sentence of the marketing definition and adding a new sentence regarding educational materials. *Marketing* means any communication, from an MCO, PIHP, PAHP, PCCM or PCCM entity to a Medicaid beneficiary who is not enrolled in that entity, that can reasonably be interpreted as intended to influence the beneficiary to enroll in that particular MCO's, PIHP's, PAHP's, PCCM's or PCCM entity's Medicaid product, or either to not enroll in, or to disenroll from, another MCO's, PIHP's, PAHP's, PCCM's or PCCM entity's Medicaid product. ***Materials and information that purely educate an enrollee of that Medicaid managed care plan on the importance of completing the State's Medicaid eligibility renewal process in a timely fashion does not meet the federal definition of marketing if the information and outreach about the eligibility renewal process is neither directed to beneficiaries who are not enrolled with that Medicaid managed care plan, nor intended to influence the beneficiary to enroll in that particular Medicaid managed care plan—or to not enroll in, or disenroll from another Medicaid managed care plan.***

~~Marketing does not include communication to a Medicaid beneficiary from the issuer of a qualified health plan, as defined in 45 CFR 155.20, about the qualified health plan.~~

**Recommendation:** Amend §438.104(a) by striking the definition of private insurance. ~~*Private insurance* does not include a qualified health plan, as defined in 45 CFR 155.20.~~

If HHS chooses to maintain the exclusion for QHPs, we recommend that it establish some guardrails to assure that beneficiaries are protected and that QHPs meet the spirit of the current regulations in some way, such as the NHeLP's recommended changes to §438.104(c).

## D. MCO, PIHP and PAHP Standards

### §438.206 Availability of services

We appreciate that HHS will continue to require plans to ensure that their provider networks are adequate, as supported by written agreements. We especially commend HHS' addition of language to this section aimed at ensuring that Medicaid plans contract with providers who are accessible to LEP enrollees and enrollees with disabilities. We suggest a small change to the text to clarify these provisions. In addition, we recommend that HHS provide additional language to clarify what is meant by the term “services” in this section. This language should clarify that all service providers—including those who provide services like durable medical equipment and orthotic devices—must be considered when the plan reviews the sufficiency of its network.

**Recommendation:** We recommend amending §438.206(b)(1) as follows: Maintains and monitors a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to all services covered under the contract, ***to the extent those services are covered by the State plan and the MCO, PIHP, or PAHP contract, in accordance with the requirements of §438.68(c) of this chapter, including access by*** those with limited English proficiency or physical or mental disabilities.

### §438.207 Assurances of adequate capacity and services

We appreciate that HHS is proposing to continue requiring plans to document their compliance with access to care requirements in §438.207. In conjunction with §438.206 and the new proposed §438.68, this section will go a long way toward ensuring that that Medicaid managed care enrollees can access covered services. Recent evidence suggests that even when states adopt generous consumer protections in Medicaid managed care aimed at ensuring access to services, access can fall short when compliance with those standards is not adequately monitored or enforced.<sup>4</sup> Thus we strongly recommend that HHS add language to this section to spell out in more detail how states should monitor plans to make sure that they are providing adequate access to care, and what kinds of monitoring tools and reporting states must employ, as described in the NHeLP's specific comments to §438.207.

### §438.208 Coordination and continuity of care

We commend HHS for updating this section to more specifically account for the needs of Medicaid plan enrollees with special health care needs and who use LTSS. The additions to this section make significant strides toward ensuring that all Medicaid plan enrollees receive coordinated, appropriate care. We support the NHeLP's specific comments on

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<sup>4</sup> See, e.g., ELAINE M. HOWELL, CAL. STATE AUDITOR, IMPROVED MONITORING OF MEDI-CAL MANAGED CARE HEALTH PLANS IS NECESSARY TO BETTER ENSURE ACCESS TO CARE (2015), available at <https://www.auditor.ca.gov/pdfs/reports/2014-134.pdf>.



§438.208 to: narrow the exceptions at §438.208(a), strengthen the care coordination requirements at §438.208(b) and protect against conflicts of interest at §438.208(c).

#### **§438.210 Coverage and authorization of services**

We commend HHS for expanding this section to give more guidance to states and plans in defining medical necessity, particularly for children. We strongly support HHS' decision to include an explicit provision that requires plans to comply with the Early Periodic Screening, Diagnostic, and Treatment (EPSDT) requirements of Medicaid. Too often, Medicaid managed care plans are not familiar with their obligations under EPSDT, and attempt to apply an adult medical necessity standard, or the standard used for private insurance enrollees, to Medicaid enrollees under 21. Adding specific language requiring plans to comply with EPSDT will go far toward ensuring that child enrollees receive the full scope of services to which they are entitled. We also suggest that HHS remove the word "chronic" from this section, as it is inconsistent with the section 1905(r)(5) of the Social Security Act (the Act), which requires states to correct or ameliorate all conditions, not only chronic ones.

We also appreciate that HHS will continue to ensure that managed care standards of medical necessity are no more restrictive than the state FFS standards. This is an area where states and plans have experienced significant confusion in the past. While it is easy for plans to understand that a state's quantitative limits set a floor for what the plans must provide, they have not always used state's non-quantitative definitions for treatment. In order to avoid this kind of legal violation, we suggest that HHS add specific language to this section to clarify that managed care medical necessity definitions should be no more restrictive than the FFS definition in terms of either quantitative or non-quantitative treatment limits. These concepts, which are widely used in the context of mental health parity, will be familiar to many plans and will help them to better assess whether their medical necessity definitions are appropriate.

**Recommendation:** We recommend amending a §438.210(a)(5) as follows: Specify what constitutes "medically necessary services" in a manner that—

- (i) Is no more restrictive—*in terms of any quantitative or non-quantitative treatment limits*—than that used in the State Medicaid *program, including FFS Medicaid*, as indicated in State statutes and regulations, the State Plan, and other State policy and procedures;
- (ii) Meets the requirements for providing early and periodic screening and diagnosis of beneficiaries under age 21 to ascertain physical and mental defects, and treatment to correct or ameliorate defects and ~~chronic~~ conditions found (EPSDT); and
- (iii) ~~Addresses the extent to which~~ **Requires** the MCO, PIHP, or PAHP ~~is responsible for~~ **to provide services covered in the contracting** ~~services that address:~~

- (A) The prevention, diagnosis, and treatment of an enrollee's disease, condition, and/or disorder that results in health impairments and/or disability.
- (B) The ability for an enrollee to achieve age-appropriate growth and development.
- (C) The ability for an enrollee to attain, maintain, or regain functional capacity.
- (D) The opportunity for an enrollee receiving long-term services and supports to ~~have~~ **that are integrated in and support full** access to the benefits of **the greater** community living.

## E. Medicaid Quality

### §431.502 State comprehensive quality strategy

We applaud HHS for requiring states to conduct a comprehensive quality strategy across all aspects of Medicaid and CHIP. We believe this effort can bring a renewed focus on the quality of care provided to Medicaid beneficiaries and presents an opportunity for HHS to focus on healthy child development and the needs of children with special health care needs. We urge HHS to require states to specifically consider pediatric quality improvement in any comprehensive strategy and use a range of pediatric measures that capture the needs of all subpopulations of children, including children with complex medical needs.

We support HHS' proposal to extend the requirements of the state comprehensive quality strategy (CQS) beyond managed care to incorporate additional types of managed care and Medicaid fee-for-service (FFS) delivery as well. While enrollment in managed care has grown considerably in recent years, more than a quarter of Medicaid enrollees still receive services through FFS, and they are often the most vulnerable groups with significant health care needs. This change will help improve monitoring and oversight of the FFS system by requiring states to set measurable goals and objectives for quality improvement and select specific measures to be collected and published at least annually on the state's website. In §431.502(b)(1), HHS proposes that each state's CQS must establish goals and objectives to "take into consideration the health status of all populations served by the Medicaid program." We suggest that HHS add language to ensure that "health status" is understood broadly to include mental health, functional status and quality of life as well. We also noted an absence of specificity in the proposed rules that recognizes that the quality measurement and performance improvement strategies differ for children and adults, and differ for healthy children compared to children with special health care needs. Similar distinctions apply to pregnant women compared to the general adult population. We believe it is vitally important that HHS bifurcate its approach to quality activities to account for these differences.

We also urge HHS to require states to include in their CQS a plan to assess, address and reduce health disparities in the state. The ACA requires "any federally conducted or

supported health care or public health programs, activities or surveys” to collect and report data stratified by race, ethnicity, sex, primary language, geography and disability status to the extent practicable. HHS has moved to implement this mandate for national Medicaid population health surveys and to incorporate it into Medicaid claims database upgrades. But quality measurement in Medicaid managed care has until recently barely addressed the issue of health disparities. Most performance data is reported in aggregate for each health plan and is not broken down by key demographic factors, including age. Stratifying quality data by the key factors called for in the ACA, as well as age, would sharpen quality improvement interventions, identify groups that continue to be left behind, and provide a status report on whether managed care is helping resolve the longstanding inequities in our health care system.

We appreciate that HHS has active programs, such as the Child Core Set and CHIPRA Quality Demonstration projects, to help states build capacity to collect data specific to children and implement quality improvement projects. We believe the CQS present an opportunity to spread the use of the pediatric Medicaid/CHIP Core set and continue to leverage and build on the pediatric quality improvement efforts through the Pediatric Quality Measures Program (PQMP). In addition to placing a stronger emphasis on pediatric quality, we encourage HHS to:

- Replace less impactful measures with validated measures coming out of the PQMP and other sources relevant to the various populations served by Medicaid;
- Ensure a pipeline of much needed pediatric quality of care and outcomes (health and cost) measures. Clinical evidence, science, and data availability changes over time, and we want pediatric measures to be responsive to these changes so they accurately reflect the quality of care for children; and
- Require the reporting of a minimum core set to move away from voluntary reporting in order to better demonstrate trends and understand how the Medicaid program operates across the country.

We would be remiss to ignore the fact that this NPRM mentions the word disparities only once, and only in the context of network adequacy, not quality measurement. And yet addressing health disparities should be a top priority in quality measurement and improvement. HHS has also produced reports with recommendations on how to improve data collection for health disparities in Medicaid and CHIP. We urge HHS to take advantage of this opportunity to advance the requirements of the ACA and ensure that states develop quality measurement programs with the capacity to evaluate health disparities and make the necessary steps to eliminate them a priority.

We cannot overemphasize that disparities and health care needs vary by age group. Children and the elderly have unique needs, as do individuals with special health care needs. Notably, since children are generally healthy, and therefore, less costly to cover, their needs are not always the focus of quality initiatives in managed care. And yet the more we do to assure the health of children before they reach adulthood, the greater

likelihood that we can reduce long term health care costs. To that end, we believe that stratification of data should always include age and health status.

**Recommendation:** Amend §431.502(b)(1) to include a broad understanding of health that includes an individual's quality of life and well-being: (1) The State's goals and objectives for continuous quality improvement, which must be measurable and take into consideration the health status *and quality of life* of all populations served by the Medicaid program.

**Recommendation:** Add a new paragraph (b)(3) to include an element that requires states to develop a plan to assess, address, and reduce health disparities. *(3) The state's plan to identify, evaluate and reduce health disparities through its quality improvement strategy, including efforts to expand the collection and reporting of performance data stratified by age, race, ethnicity, sex, primary language, geography and disability status and actions taken to reduce health care disparities.*

#### **§431.504 State comprehensive quality strategy development, evaluation, and revision**

We support HHS' proposal to require states to solicit stakeholder feedback and conduct a public comment process during the drafting and revision of the state CQS. We also agree with the requirement that states consult with the Medical Care Advisory Committee (MCAC), which will help clarify and expand the role of these required stakeholder advisory groups.

However, we strongly urge HHS to strengthen and add specificity to this requirement for public input. Without clear requirements to solicit, consider and respond to public comment, meaningful stakeholder engagement is difficult to secure. In other Medicaid contexts that require formal comment, some states have buried hearing and comment notices in obscure locations on their website, produced draft plans so lacking in detail that no meaningful comment is possible, or submitted to HHS "revised" drafts that do not include a single change to the original proposal. To avoid such problems and ensure meaningful stakeholder engagement in the proposed CQS drafting process, we urge HHS to add significant detail to flesh out its vision for a robust CQS public comment process. We believe the best recent model for transparent public engagement would be the regulations governing the comment process for §1115 demonstration projects. This approach includes a 30-day comment period at the state level, a requirement for at least two public hearings and the posting of a detailed draft plan on the state website, and a requirement that the state include a response to public comments collected (along with a description of whether it incorporated these changes) in the draft it submits to HHS. In addition, stakeholders have another 30-day comment period at the federal level for the revised draft. HHS posts all these documents in a single place on its website, which makes it easier to track when new §1115 proposals are up for federal review.

If HHS chooses not to include a federal level comment period for CQS, it should at least require in the regulation that states:

- Provide adequate notice of a public comment period including prominent display on the state website;
- Conduct well-publicized public hearings to educate stakeholders on the details of the proposed CQS and give them the opportunity to provide direct feedback;
- Post a detailed and comprehensive draft CQS for comment for at least 30 days;
- Accept public comments in multiple manners, including electronically, by phone and through the mail; and
- Submit to HHS (along with its final CQS) a detailed response to stakeholder comments collected, including reasons for altering or not altering the draft in response to those comments.

**Recommendation:** Amend 431.504(a) as follows:

(a)(1) Obtain the input of the Medical Care Advisory Committee, required by §431.12, beneficiaries, and other stakeholders (including Tribal consultation ***and consultation with the state LTSS stakeholder advisory committee required by §438.70***, as appropriate) in the development of the comprehensive quality strategy (and any revisions) and

(2) Make the strategy available for ***meaningful*** public comment before submitting the strategy to HHS for review. ***As part of such public comment process, the State must:***

***(i) Post a comprehensive draft of the comprehensive quality strategy that contains a sufficient level of detail to ensure meaningful input from the public on the state's public Medicaid website prior to and throughout the public comment process;***

***(ii) Provide at least a 30-day notice and comment period, and the public notice shall include all of the following information:***

***(A) A summary describing the purpose and content of the comprehensive quality strategy and the public comment process;***

***(B) The locations and Internet address where copies of the draft quality strategy are available for public review and comment;***

***(C) Postal, Internet and email addresses where written comments may be sent and reviewed by the public, and the minimum 30-day time period in which comments will be accepted; and***

***(D) The location, date and time of at least two public hearings convened by the State to seek public input on the demonstration application.***

***(iii) Publish its public notice process, public input process, planned hearings, and the draft quality strategy in a prominent location on either the main page of the public website of the State Medicaid agency or on a quality strategy-specific webpage that is linked in a readily identifiable***

*way to the main page of the State agency's website. The State must maintain and keep current the public website throughout the entire public comment and review process;*

*(iv) Publish an abbreviated public notice which must include a summary description of the quality strategy, the location and times of the two or more public hearings, and an active link to the full public notice document on the State's website in the State's administrative record in accordance with the State's Administrative Procedure Act, provided that such notice is provided at least 30 days prior to the submission of the comprehensive quality strategy to HHS, and in the newspapers of widest circulation in each city with a population of 100,000, or more, provided that such notice is provided at least 30 days prior to the submission of the demonstration application to HHS;*

*(v) Utilize additional mechanisms, such as an electronic mailing list, to notify interested parties of the comprehensive quality strategy;*

*(vi) At least 20 days prior to submitting the quality strategy to HHS for review, the State must have conducted at least two public hearings, on separate dates and at separate locations, regarding the State's quality strategy at which members of the public throughout the State have an opportunity to provide comments. The State must use telephonic and/or web conference capabilities for at least one of the two required public hearings to ensure statewide accessibility to the public hearing.*

*(vii) Provide in its submission to HHS a response to comments collected and to input received from the MCAC, the LTSS stakeholder group, tribes and other stakeholders. The states response must include revisions made (or not made) related to those comments and must be posted on the public website of the State Medicaid agency.*

#### **§438.310 Basis, scope and applicability**

We support HHS' expansion of the scope of quality measurement requirements to include PAHPs and, for certain provisions, PCCM entities. We agree that as PAHPs have expanded to encompass a broader array of services, they should be subject to the quality standards required of other managed care programs.

#### **§438.320 Definitions**

We believe the term "access" should include a cross-reference to §438.208, because adequate care coordination and protections moving between providers are important components of access to care, particularly for individuals who require LTSS. The care coordination provision at §438.208 includes standards for direct access to specialists and requires the MCO to have adequate and appropriate staffing to properly manage care, identify individuals with chronic conditions or LTSS needs, and conduct needs assessments and treatment and service plans for such individuals. These facets of care planning are

central to the concept of “access” and should be considered as part of the validation of MCO, PIHP and PAHP networks.

**Recommendation:** Amend the definition of access in §438.320 as follows: Access, as it pertains to external quality review, means the timely use of services to achieve the best outcomes possible, as evidenced by successfully demonstrating and reporting on outcome information for the availability and timeliness elements defined under §438.68 (Network adequacy standards), ~~and~~ §438.206 (Availability of services) **and §438.208 (Care coordination).**

Similarly, the definition of “external quality review” refers to “health care services.” We suggest deleting “health care.” Alternatively, we suggest defining the term “health care services” to broadly include all Medicaid services covered under the contract, including LTSS.

**Recommendation:** Amend the definition of “External quality review” in §438.320 as follows: *External quality review* means the analysis and evaluation by an EQRO, of aggregated information on quality, timeliness, and access to **all the health care** services that an MCO, PIHP, or PAHP, or their contractors furnish to Medicaid beneficiaries.

**Recommendation:** Amend the definition of “quality” in §438.320 as follows: Quality, as it pertains to external quality review, means the degree to which an MCO, PIHP, or PAHP increases the likelihood of desired ~~health~~ outcomes of its enrollees through...

**Recommendation:** Add a definition for “outcomes” in §438.320: ***Outcomes, as they pertain to external quality review, are changes in patient health, functional status, quality of life, goal achievement, or ability to live and engage in community life that result from health care or supportive services.***

Finally, the use of the term “review” in the definition of “validation” could be construed to preclude the creation of new data as part of the validation process, such as through a secret shopper or beneficiary survey used to validate a plan’s network adequacy. We suggest adding a reference to “direct testing of” after “review” to ensure that validation encompasses the types of direct testing HHS proposes will comprise the network adequacy validation protocol laid out in §438.358(b)(4). We also suggest that HHS define the term “direct testing” in the regulations for better clarity. If this change is not made, we recommend requiring direct testing in the EQR protocols that are issued as subregulatory guidance.

**Recommendation:** Amend the definition of validation in §438.320 as follows: *Validation* means the review **and, when applicable, direct testing**, of information, data, and procedures, to determine the extent to which they are accurate, reliable, free from bias, and in accord with standards for data collection and analysis.

**Recommendation:** Add a definition of “direct testing” in §438.320 as follows:  
*Direct testing, as it pertains to external quality review, means the proactive testing of managed care plans’ compliance with state standards and requirements, including the accuracy of information maintained and reported by managed care plans. Examples of direct testing include making direct calls to network providers to determine availability and accessibility, conducting systematic evaluations of consumer service calls, and comparing encounter data against a statistically valid sample of individual medical records.*

### **§438.330 Quality assessment and performance improvement program**

On the whole, we support the changes to this section: applying the requirements to PAHPs and establishing a process with active stakeholder input to develop required, standardized measures and select national topics for Performance Improvement Projects (PIPs). This is consistent with HHS’ ongoing work to develop and implement the adult and children core measure sets. States have had several years to voluntarily consider and expand the use of those sets. Having a standard core set of measures for other key populations can enable comparison across states through mechanisms such as the proposed quality rating system and, when coupled with federally selected PIP topics, helps HHS establish and monitor national priorities for health care improvement. National PIPs could help innovation and sharing of best practices for improvement in such priority areas. States will retain flexibility to add other measures to their required set.

We also strongly recommend that HHS provide additional requirements to flesh out the stakeholder engagement and public comment process for selecting national measures and PIP topics. We suggest that HHS, at the very least, lay out in the regulations steps for soliciting public comment that include an outreach and education component, a minimum comment period and requirements to include responses to public comments in subsequent drafts. Establishing a quality task force that includes balanced and meaningful representation from various advocates, Medicaid beneficiaries, and their families would help increase awareness and expertise for future revisions of and additions to the core measure set. This could also be achieved through regular required consultations with the state MCACs and, as applicable, LTSS stakeholder advisory groups.

While we understand that a particular measure may not be relevant for a certain population, we strongly recommend that HHS strictly limit its proposed exceptions process by enumerating a set of specific reasons when a state may obtain an exception and setting time limits on how long an exemption could last without review and consideration for an extension. HHS requested comment on the possible exceptions process. We agree with HHS that legitimate exceptions to list could be excluding a measure that is irrelevant to the managed care covered population in a state and a measure of the quality of a service not covered by, or relevant to, the managed care contract.

We ***strongly disagree*** with the preamble suggestion that a state might qualify for an exemption if it surpasses a defined threshold for multiple years. For many measures, such



as certain vaccinations or the frequency of “never events,” a threshold of 90 percent would not be considered successful. Even if HHS set appropriate thresholds for each national measure, the exemption process leaves no mechanism to prevent against deterioration in performance after the exemption is granted – a deterioration that may go unnoticed because the state is no longer collecting data on that metric. Moreover, while the overall managed care population might exceed a given threshold; significant disparities may remain for important subpopulations. Allowing a state to then exempt its managed care entities from reporting that metric could thus undermine HHS’ broader efforts to identify and reduce health disparities across key demographic groups. If HHS were to go forward, against our recommendation, and allow this type of exemption, it should require that the threshold also demonstrate that no significant disparities exist and it should limit the exception to no more than two years.

We encourage HHS to clarify the relationship between the state and national measures and PIP topics selected under §438.330(a)(2) and the state measures selected under §431.502(b)(2). The proposed comprehensive quality strategy is meant to apply statewide across delivery systems; but it is unclear if the national measures selected under §438.330 for all managed care plans would also apply in the Medicaid FFS context, or if States could pick entirely different measures to apply to FFS.

We applaud HHS for requiring PCCM entities to establish and maintain mechanisms to detect over- and underutilization of services under §438.330(b)(3), like other managed care entities. Such mechanisms can be important tools to detect potential misuse, identify access barriers and evaluate network adequacy.

Paragraph (c)(4) requires that states contracting with MCOs, PIHPs or PAHPs to cover LTSS must develop additional metrics related specifically to the quality of LTSS. While we recognize that LTSS performance measurement, specific to both children and adults, is not well developed, this requirement will help advance better and more comprehensive metrics. We support the requirements in this provision to evaluate quality of life, rebalancing, and community integration. We urge HHS to also require states to include measures related to care coordination and the needs assessment process, in states that implement this option.

**Recommendation:** Amend §438.330(a)(2) as follows: HHS, through a public notice and comment process in consultation with States and other stakeholders, may specify performance measures, *for both pediatric and adult populations*, for collection in accordance with paragraph (c) of this section, a methodology for calculating quality ratings, and topics with performance indicators for performance improvement projects in accordance with paragraph (d) of this section to be required by States in their contracts with MCOs, PIHPs, and PAHPs.

**Recommendation:** Amend §438.330(a)(2)(ii) as follows: A State may apply for an exemption, *for no more than 2 years*, from collecting and reporting on the performance measures or performance improvement projects established under

(a)(2) of this section, by submitting a request, in writing, to HHS which details the reason, ***as described in (A) and (B)***, for such an exemption.

**Recommendation:** Add limited reasons for which a state may receive an exemption at §438.330(a)(2)(ii) as follows: ***(A) if the measure is not applicable to the covered population; or (B) if the measure is only relevant to a service or services not covered in the MCO contract.*** If HHS, against our recommendation, permits exemptions based on sustained achievement, the thresholds must be appropriate for each measure and states should have to prove that no significant disparities exist for key demographic groups prior to receiving a time-limited exemption.

**Recommendation:** Amend paragraph (c)(4) as follows: *LTSS performance measurement.* The State must require, through its contracts, each MCO, PIHP, and PAHP that provides LTSS services to include, as a part of its performance measurement activities under this paragraph and in addition to other measures required of all MCOs, PIHPs, and PAHPs, measures that assess the quality of life of ***both pediatric and adult*** beneficiaries, ***the timeliness and effectiveness of the needs assessment process, the efficacy of care coordination measures*** and the outcomes of the MCO, PIHP, or PAHP's ***activities related to rebalancing, self-direction of services (if applicable),*** and community integration activities for beneficiaries receiving LTSS.

#### **§438.332 State review and approval of MCOs, PIHPs, and PAHPs**

Generally, we are not opposed to requiring that states develop specific accreditation standards for their contracted MCOs, PIHPs and PAHPs, provided that states solicit public comment in establishing those standards and subsequently make them readily available to the public. This proposed rule allows states to set their own review standards, but it seems much more likely that states will instead choose to deem compliance based on accreditation by an approved private independent entity. We have a number of significant reservations about this approach.

*The process of setting standards for Medicaid and CHIP should include input from the public.* But, the regulation does not include a mechanism allowing the public to review or provide input into what those standards actually are.

*The public should have access to the results of the actual accreditation survey and report, not just the final level of accreditation achieved by the plan, if the state accepts accreditation by private entities.* Private accrediting entities, such as the National Committee for Quality Assurance (NCQA) and URAC, do not make their accreditation standards readily available to the public, sometimes claiming them to be “proprietary property.” While available for purchase, these standards may be quite expensive. Private entities’ standards and measures must be readily and publicly available at no or nominal cost, or should be determined by the state after a robust stakeholder engagement process.

*The accreditation process should be specific to the Medicaid business line of a participating MCO, PIHP or PAHP, yet this rule does not specify this criterion.* Medicaid populations are different from commercial groups and have unique needs. If states are allowed to use an MCO-wide accreditation standard, it may not be a reliable predictor of how well that MCO will be prepared to manage care for Medicaid populations, especially with regards to children with special health care needs or LTSS, which have not historically been a focus for managed care companies and are not covered under typical commercial or Marketplace insurance plans. Accreditation should accordingly be specific to the Medicaid business line and should be adapted to incorporate state-specific standards as well as considerations that adhere to the unique needs of Medicaid populations.

*Accreditation should not undermine other quality assurance efforts.* The proposed rule's expansion of required accreditation, which is written to strongly encourage states to make use of private accrediting agencies, could easily end up replacing many, if not most, of the key elements of EQR, and perhaps in a less timely, less accountable and less effective manner. We ***strongly oppose*** the proposal to expand EQR nonduplication exceptions to allow information gathered from private accreditation entities to be used in lieu of the validation of performance improvement projects and performance measures due to concerns about timeliness, transparency, the independence of accreditation validators and the vagueness of the "substantially comparable" standard in proposed §438.360. *See discussion of §438.360 below for more detail.*

**Recommendation:** Amend §438.332(b) as follows: Compliance deemed on the basis of accreditation by a private independent entity. (1) The State may elect to use proof of MCO, PIHP, or PAHP accreditation by a private independent entity recognized by HHS under 45 CFR 156.275(c) or approved under §422.157 of this chapter to satisfy the requirement described in paragraph (a) of this section ***if it is specific to the Medicaid population.***

**Recommendation:** Amend §438.332(b)(2)(i) as follows: Accreditation status, survey type, or level (if applicable) ***and the standards and measures used.***

#### **§438.334 Medicaid managed care quality rating system**

We understand the potential value of a robust and well-designed quality rating system for Medicaid managed care plans. Such tools can provide consumers with user-friendly information that can help them make informed selections from a variety of options. A quality rating system can also encourage transparency and even strengthen the oversight process. However, a poorly designed or executed quality rating system can do quite the opposite by potentially giving plans an undeserved imprimatur of excellence.

Any effective quality rating system must include a transparent process for addressing the demographic differences between covered populations for different plans. On the one hand, if a plan does a particularly good job with care management for chronic conditions and attracts more individuals with chronic conditions, its performance on health outcome measures may actually *go down* relative to another plan that serves a healthier population.

On the other hand, if a plan knows its quality outcomes will be risk adjusted to account for sicker members, it may have less incentive to focus on improving outcomes for those individuals. In either case, there must be a clear and transparent process for addressing risk adjustment for any Medicaid quality rating system. This will be particularly important should a state (or HHS) decide to implement or apply a similar system to its FFS populations.

It is unclear what HHS means by “affordability” in subparagraph (a)(2)(iii). Out-of-pocket expenses for Medicaid beneficiaries do not vary by health plan, so we interpret this phrase to mean “affordability” in terms of overall costs to the Medicaid program. While this may be an important goal for the State agency, it is not strictly relevant to the quality of care offered by a health plan, and may in fact run counter to the aims of a quality rating system intended for consumer use. For example, if affordability factors into a plan’s rating, one would expect that a plan that is cheaper for the Medicaid program may rate equally to a slightly more expensive plan with better health outcomes. From the point of view of a beneficiary, the second plan would be the better choice, but the quality rating system might not reflect that. We believe the term “efficiency” better addresses the triple aim of better care, better health outcomes, and affordability. We recommend that HHS delete “affordability” as a component of the quality rating system (unless affordability specifically refers to the individual’s ability to pay out-of-pocket expenses).

Finally, the preamble discusses the elements of a public comment and stakeholder engagement process to design and implement the quality rating system. HHS should ensure that detailed requirements for this process are clearly outlined in the regulation. The proposed regulation refers only to the federal public process for determining which measures are required and how that data will be collected. That public comment process does not include how the different measures will be weighted in an overall quality rating system, nor how States will account for differences in covered populations between plans. The regulations should clearly indicate how such key elements would be included in the federal (or state) stakeholder process. In addition to looking at CCIIO’s public engagement approach, we urge HHS to model this process after the transparency and public engagement requirements for the §1115 demonstration approval process. Without clear regulatory language, key stakeholder engagement and buy-in will likely be lost in the planning process. Certainly, the regulations should require any state that elects to design an alternative process to engage in a robust public comment process before receiving HHS approval.

**Recommendation:** Amend paragraph §438.334(a)(2) as follows: The quality rating system must be based on the following ~~three~~ **four** components:

- (i) Clinical quality management **and, if applicable, management of LTSS.**
- (ii) Member **and provider** experience.
- (iii) Enrollee access to care**
- ~~(iii)~~ **(iv)** Plan efficiency, ~~affordability~~, and management.

**Recommendation:** Add a new paragraph (a)(4) to ensure consumers will understand how to use the tool: **The State must conduct sufficient outreach,**

***notice and education to ensure that users can readily identify and understand the strengths and limitations of the rating system, including but not limited to information on how LTSS factors into the rating and how the rating system weights plan ratings based on enrollment demographics.***

**Recommendation:** Amend paragraph (c) to require states that elect to develop an alternative rating system to establish a robust stakeholder engagement and public comment process similar to the requirements for §1115 demonstrations as follows: (c) *Alternative quality rating system.* Upon HHS approval, a State may opt to use an alternative quality rating system that utilizes different components than those described in paragraph (a)(2) of this section, incorporates the use of different performance measures than those described in paragraph (a)(3) of this section, or applies a different methodology from that described in paragraph (b) of this section. ***HHS will not approve such an alternative system unless the state's proposal has satisfied public comment, notice and consultation requirements at least as stringent as those for §1115 demonstration projects described in 42 C.F.R. §431 Subpart G. States must include evidence of consultation with the state MCAC, the state LTSS stakeholder advisory group, and other stakeholders, including health consumer advocacy coalitions in the state and representatives of both the pediatric and adult populations.***

#### **§438.340 Managed care elements of the state comprehensive quality strategy**

We support the additional elements HHS has proposed requiring states to include in their CQS. We ask HHS to clarify the relationship between the state-selected quality metrics described in §431.502(b)(2) and the state-selected metrics described in §438.330(a)(2)(i). Additionally, it is not clear whether or how metrics selected in the HHS public comment process described in §438.330(a)(2) would apply to a state's Medicaid FFS system.

**Recommendation:** Clarify the relationship between the metrics described in §431.502(b)(2) and those in §438.330(a)(2).

#### **§438.350 External quality review**

HHS has proposed several very positive changes for Medicaid EQR. We support the proposal to extend EQR to include PAHPs that contract with the state, to increase EQR availability, and especially the proposal to add a new mandatory EQR-related activity focusing on actively testing MCO, PIHP and PAHP managed care networks. On the other hand, HHS appears to have simultaneously weakened EQR through the broadening of the nonduplication provision in §438.360 and the reduction of federal matching rates for EQR and EQR-related activities conducted on non-MCO managed care plans. We describe these concerns below.

Notably, the EQR may be appropriate for certain PCCM entities that participate in shared savings, incentive payments, or other arrangements for financial reward for improved

quality outcomes, per §438.3(r). With the rapid evolution and hybridization of delivery systems, such models must also be accountable for delivering quality care, and EQR review is one appropriate approach. We do not agree with the proposed language that states should have sole discretion over whether EQR should be required for such PCCM entities. We believe the regulation should presume that PCCM entities with a financial stake in quality outcomes would be subject to EQR, and that the state should have to justify not requiring EQR for such PCCM entities to the Secretary. At the very least, we recommend amending the proposed language to clearly give the Secretary the option to require EQR for such entities.

We also propose clarifying language in paragraph (a)(3) to indicate that information obtained from private accreditation or Medicare can only be used if the applicable requirements have been satisfied.

**Recommendation:** Add the following language to paragraph (a)(3): The information used to carry out the review must be obtained from the EQR-related activities described in §438.358 or, *if applicable*, from a Medicare or private accreditation review as described in §438.360.

**Recommendation:** Add the following language to paragraph (b): *Consistent with the requirements of §438.3(r),* Aa State ~~may~~ *must* require that a qualified EQRO performs an annual EQR for each PCCM entity *with a State contract that provides for shared savings, incentive payments or other financial reward for improved quality outcomes, unless the State provides written evidence that EQR would be inappropriate for such entity and the Secretary approves the exemption* ~~consistent with the requirements of §438.3(r).~~ If an EQR is performed, the requirements...

#### **§438.354 Qualifications of external quality review organizations**

While this section is largely unchanged from the current regulations, we recommend adding language to the independence protections to ensure that an organization with ties to an MCO, PIHP, or PAHP may not qualify as an EQRO to review competitors in the same service area. We believe this closes a potential loophole in the independence protections. We suggest that, because EQR may be required of certain PCCM entities, the independence provision also list controlling relationships with PCCM entities as a disqualifying factor for EQROs. We believe this simply corrects a drafting oversight and reflects the intention of HHS' proposed changes. Similar additions may also be appropriate for other sections in the EQR regulation.

We support the prohibition that entities that conduct accreditation reviews on contracting MCOs, PIHPs, PAHPs, or PCCM entities may not perform as EQROs.

**Recommendation:** Throughout subsection (c) add “PCCM entity” to the list of managed care organizations, such that “MCO, PIHP, or PAHP” becomes “MCO, PIHP, PAHP, or PCCM entity.”

**Recommendation:** Add the following language to subparagraph (c)(3)(i), stating that an EQRO may not: (i) Review a particular MCO, PIHP, ~~or PAHP~~, **or PCCM entity, nor review any other MCO, PIHP, PAHP or PCCM entity operating in the same service area as such particular MCO, PIHP, PAHP, or PCCM entity**, if either the EQRO or the MCO, PIHP, or PAHP, or PCCM entity exerts control over the other (as used in this paragraph, ‘control’ has the meaning given the term in 48 C.F.R. §19.101) through—

**Recommendation:** Add the phrase “or expected” to subparagraph (c)(3)(v), stating that an EQRO may not: (v) have a present, ~~or known~~ **or expected** future, direct or indirect financial relationship with an MCO, PIHP, ~~or PAHP~~, **or PCCM entity** that it will review as an EQRO.

#### **§438.356 State contract options for external quality review**

We support the contract options provision as written, including the requirement that states follow an open, competitive procurement process. The regulations at 45 C.F.R. 75 require that each Request for Proposals (RFPs) be publicized, but does not specify that states post RFPs on the state Medicaid website. We also strongly recommend that the public have a role in reviewing and commenting on the details of the RFP.

**Recommendation:** Add the following sentence to §438.356(e): For each contract with an EQRO described in paragraph (a) of this section, the State must follow an open, competitive procurement process that is in accordance with State law and regulations. In addition, the State must comply with 45 C.F.R. Part 75 as it applies to State procurement of Medicaid services. ***Notwithstanding State law, the State agency shall post its Request for Proposals on a website that is accessible to the public and provide a reasonable public comment period prior to beginning the bidding process.***

#### **§438.358 Activities related to external quality review**

As Medicaid increasingly employs capitation and accountable care as the preferred payment model, robust, independent quality review becomes an even more critical component to counteract financial incentives to limit coverage of necessary care. To this end, we commend HHS for proposing to require EQR to include validation of provider network adequacy. The preface suggests this new EQR protocol will include direct testing methods such as secret shopper surveys, to validate network adequacy for MCOs, PIHPs, PAHPs and PCCM entities required to conduct EQR under §438.350. The 2014 HHS OIG reports cited in the preamble demonstrate the efficacy and importance of directly evaluating provider networks for compliance, access and availability. They plainly show

that the “compliance reviews” normally conducted through EQR can be pro forma and have not effectively evaluated actual compliance in the area of network adequacy. Moreover, states that engage in direct testing of compliance, such as calling providers to assess availability and verify the accuracy of provider directories, or calling plan customer service to evaluate wait times and responsiveness, are far more likely to identify violations in access and timeliness standards.

We support HHS’ imposition of the requirement to validate network adequacy, but believe it should be strengthened. As the OIG reports revealed, an absence of violations of requirements can indicate a weak and passive review process rather than exceptional plan performance. We believe it unlikely that managed care compliance problems are limited to provider networks. For this reason, we recommend that HHS expressly require direct testing in other compliance areas as well, including care coordination, utilization management, and service authorization. Under our recommendation, a state would have to conduct annual direct testing of at least a subset of managed care quality standards each year. This requirement would stand apart from the existing requirement to require comprehensive compliance review at least every three years. Parameters for how states or HHS would prioritize areas for direct testing under this provision could be determined through subregulatory guidance. We also recommend that the annual EQR technical report include an accounting of all violations identified by the state or EQRO during the compliance review and explain corrective actions taken.

The provision requiring validation of network adequacy should also be strengthened. First, while the preamble explains that direct testing will be described in future guidance detailing the network adequacy validation profile, this oversight technique is important enough that it should be expressly described in the regulation itself. Second, HHS should clarify that the validation of network adequacy includes three interrelated but distinct components: network adequacy standards (which must include at least time and distance standards), timeliness and availability standards (described in detail in §438.206), and the accuracy of provider directories (described in §438.10(h)). As currently written, the EQR would only have to validate State network adequacy standards required in §438.68, and it does not clearly encompass the other two fundamental components. HHS’ description of the proposed new EQR protocol does envision activities such as testing provider directories, but the preamble also appears to distinguish the requirements at §438.206 from network adequacy standards when it claims that: “An assessment of compliance with §438.206 (availability of services) would occur as part of the mandatory compliance review described in §438.358(b)(3).” However, that review occurs only once in three years, not annually. An external reviewer should measure provider accessibility and timely availability annually because it is fundamental to ensuring that enrollees can find a provider and get the services they need when they need them. We strongly recommend that HHS revise the provision requiring validation of network adequacy to cross reference §438.206 and §438.10(h) along with §438.68. These include precisely the sort of protections that direct testing should evaluate.

Finally, we recommend that HHS add two mandatory EQR activities. We believe a full review and accounting of grievances and appeals should be a mandatory EQR-related



activity. Such a review can provide states with another mechanism to identify systemic issues and act upon them. Similarly, requiring states or EQROs to collect data directly from enrollees, in the form of focus groups or beneficiary surveys, will provide a useful cross check for broad-based CAHPS surveys and can help states directly evaluate a plan's compliance with other standards, such as care coordination and utilization management. Such consumer surveys and focus groups are currently optional EQR-related activities.

**Recommendation:** Amend §438.358(b) as follows, including PCCM entities at paragraph (3), adding a new paragraph (4) (renumbering (b)(4) to (b)(5)), moving paragraph (c)(2) to (b)(6), and adding new paragraph (7):

(3) A review, conducted within the previous 3-year period, to determine the MCO's PIHP's, ~~or~~ PAHP's, **or PCCM entity's** compliance with the standards set forth in subpart D and the quality assessment and performance improvement requirements described in §438.330.

***(4) Validation by direct testing of compliance with at least a subset of the standards set forth in subpart D and the quality assessment and performance improvement requirements described in §438.330 during the preceding 12 months.***

~~(4)(5)~~ Validation of MCO, PIHP, ~~and~~ PAHP, **and PCCM entity** network adequacy during the preceding 12 months to comply with requirements set forth in §438.68-, **§438.206, §438.10(h) and §438.208(b) and (c). This validation must include direct testing of the plan's provider network through mechanisms such as secret shopper surveys or direct calls to network providers to evaluate availability and accessibility.**

***(6) Administration or validation of quantitative and qualitative research with enrollees, such as*** consumer surveys and focus groups, conducted during the preceding 12 months examining consumer experience and care quality.

***(7) A review and analysis of complaints, grievances, and appeals filed in the preceding 12 months with each MCO or PHP, including their outcomes, to identify systemic problems and recommend potential remedies.***

**Recommendation:** Strike paragraph (c)(2) to conform with the recommended changes as follows: ~~(c)(2) Administration or validation of consumer or provider surveys of quality of care;~~

#### **§438.360 Nonduplication of mandatory activities**

The major expansion of required Medicaid accreditation proposed in §438.332 has serious implications for the EQR process. While we recognize the merit of minimizing unnecessarily duplicative oversight activities, the changes proposed for this section appear to directly contradict and undermine other proposed changes to strengthen the EQR

process. The only example described in the preamble of how this new process would work frankly raises more questions than it answers. We strongly oppose the proposed changes to the non-duplication provision, and recommend that HHS abandon its proposed expansion of the nonduplication provision. At the very least, HHS must address the multiple concerns and apparent conflicts the proposed changes raise and ensure that the proposed expansion of private accreditation does not effectively replace independent EQR. These concerns include a lack of transparency, a potential for increased time lag for data, questions about the independence of validation tests from private accreditors, and concerns about the comparability of Medicaid with commercially insured populations.

The proposed changes would expand the current nonduplication provision to allow states to use information from private accreditors in lieu of mandatory EQR-related activities for the validation of PIPs and performance measures. In previous rule-making that finalized the current regulations, HHS justified excluding these activities from the nonduplication provision because the private accreditation review often encompasses an MCO or PIHP's commercial lines of business. HHS argued that the population served by commercial insurance is dissimilar to the population served by Medicaid, and that EQR should only evaluate performance measures and PIPs specific to the Medicaid population. It is not clear what has changed to justify this proposed policy change. HHS has not proposed or even suggested requiring that MCOs, PIHPs and PAHPs have accreditation specific to their Medicaid line of business. Nor has it provided any justification for how the validation of PIPs and performance measures conducted on a commercial population can be considered duplicative of validation of these measures for a Medicaid-specific population. Even if HHS resolves the issue of dissimilar populations – such as through requiring Medicaid-specific accreditation for Medicaid-specific standards – the nonduplication provision raises other concerns and problems, such as timing. First, the preamble notes that states can use information from private accreditation within the previous three years in lieu of mandatory EQR activities. This seems to contradict the requirement in §438.358(b) that EQR validate performance measures and PIPs annually. It is therefore not clear whether a state would be permitted to use the same accreditation data for three years, or only in the first year after the accreditation survey was completed. Even if HHS limits the use of private accreditation data to the first year after accreditation, this practice is likely to exacerbate one of the long-standing criticisms of EQR – that the data in final reports often lags significantly. If the accreditation review covers data from a prior year, and it can be used in lieu of EQR validation in the first year after completion, the data used to validate performance measures and PIPs for the purposes of EQR would be up to two years old. Elsewhere in this proposed regulation, HHS seeks to alleviate the time lag problem by requiring states to finalize the annual EQR technical report by April 30 each year (for data collected within the last 15 months), but this expansion of the nonduplication provision appears to make the time lag worse.

The example of nonduplication described in the preamble raises additional concerns about how the state will apply the “substantially comparable” standard. HHS suggests that an MCO, PIHP or PAHP with NCQA accreditation must have undergone a validation process for its HEDIS measures, and that if the accreditation review standards are “substantially comparable” to the standards laid out for that activity in the EQR protocols, then the state

could use the data from the accreditation in lieu of conducting a separate EQR validation. But it is not clear what would happen if this same state requires other performance measures that are not part of HEDIS. For example, if the state includes LTSS in its managed care contracts, or any other non-HEDIS measures, the state should still be responsible for contracting with an EQRO to validate all the non-HEDIS measures it requires separately. If accreditation standards are hidden behind a paywall or a claim of “proprietary property,” advocates will have limited ability to examine whether the accreditor’s validation standards are actually “comparable” to the EQR protocol. HHS must make clear who will oversee the state’s decision in such cases. It is also unclear how deep the “review and analysis” of accreditation reports by EQROs will be. As written, we are concerned that the EQRO will not reanalyze the raw data, but rather simply reread a report that describes the accreditor’s analysis.

This expansion of the nonduplication provision also raises questions about the independence of the entities that validate measures for private accreditors. In earlier responses to comments on its 2012 EQR protocols, HHS has identified at least one “approved HEDIS auditor” that is paid by the MCO, and so, according to HHS, it is not “independent” under §438.354. While we agree with HHS that this should be a disqualifying factor, the nonduplication provision proposed here makes no reference to the applicability of the competence and independence standards in §438.354. Nor does it provide any mechanism to ensure that private accreditors’ subcontractors will be properly examined to show they meet the competence and independence standards. Finally, one of the most important and potentially impactful changes to EQR is the requirement that states incorporate direct testing into their EQR review. As noted above, we believe that the 2014 OIG reports on network adequacy reveal a major shortcoming of the current EQR compliance review process, and demonstrate the value of using direct testing to review MCO compliance with other Medicaid standards beyond network adequacy, such as care coordination, notice and due process, and utilization management.

We strongly urge HHS to require states to expand the use of direct testing as part of the mandatory EQR requirement to review MCO, PIHP, and PAHP compliance with the standards set forth in subpart D and in §438.330. In other words, if a state uses information from a substantially comparable accreditation compliance review in lieu of EQR, it would still have to do additional direct testing of some aspect of an MCO’s compliance each year. Alternatively, HHS could require direct tests of compliance as part of the Medicaid accreditation process.

**Recommendation:** Revert to the current nonduplication provision at §438.360 and add requirements that information from an authorized private accreditor used in lieu of an EQR-related activity must come from entities that meet the independence and competency standards described in §438.354, apart from the proposed §438.354(c)(3)(iv).

#### **§438.362 Exemption from external quality review**

We support the changes to this section to limit this exemption to MCOs.

#### **§438.364 External quality review results**

We support the recommended additions that require EQR annual technical reports to include results from performance measures and from PIPs alongside the validation results. States are not currently required to report these results, though many already do. This change will make it easier to locate data by centralizing it in a single report that must be posted on the state Medicaid website. We also recommend that technical reports monitor compliance violations to make it easier to track and compile violations across plans and states. Such data was included in the OIG reports on network adequacy and helped show the value of direct testing in that context.

We also support the changes in this section that require states to post the annual EQR technical report on their Medicaid website. Because part of the EQR involves providing annual recommendations for improvement and evaluating how well plans have responded to prior recommendations over time, we recommend that HHS require plans to maintain an archive of past EQR technical reports on their Medicaid website. This represents minimal added burden for the state, but provides a much richer longitudinal perspective of how plans perform over time.

**Recommendation:** Add a requirement that EQR technical reports account for all violations identified by the state or EQRO during the compliance review and detail corrective actions taken.

**Recommendation:** Add language to the second sentence of paragraph §438.364(b)(2) to require states to create and maintain an archive of annual technical reports on its website, as follows: The state must make the most recent copy of the annual EQR technical report publicly available on the state's website required under §438.10(c)(3) *and maintain on such website an archive of prior technical reports dating back at least five years or to the inception of the State's managed care program.*

#### **§438.370 Federal Financial Participation**

HHS explains that it has reviewed the statutory language relating to the applicability of enhanced federal matching rates to EQR and EQR-related activities. Specifically, HHS is reinterpreting the statute to limit the enhanced 75 percent federal match to EQR activities for MCOs. If finalized as proposed, EQR of PIHPs, PAHPs, and PCCM entities will only be eligible for the standard 50 percent administrative matching rate. The implications of this policy change for EQR are substantial. States with extensive PIHP programs, like California's county mental health system, will have much less incentive to conduct robust EQR of these entities due to the added costs. Moreover, this change undermines states' incentive to contract with EQROs to conduct EQR-related activities described in §438.358 for non-MCO entities. A state may conduct these activities internally, or contract with a

non-EQRO agent that may not meet all the requirements for competence and independence. Under this proposed change, the non-qualified agent would be reimbursed at the same standard administrative matching rate.

It seems contradictory to expand EQR to PAHPs and some PCCM entities while at the same time effectively reducing the EQR matching rate for those same entities. We are not convinced by HHS' argument supporting this change. The extension of enhanced match for EQR of PIHPs has been uncontroversial for more than a decade, and elsewhere in this same regulation HHS has proposed to extensively utilize its authority under section 1902(a)(4) of the Act to implement methods of administration "necessary for the proper and efficient operation of the plan." Given the potential negative effects of reducing the match, and the striking similarity of EQR for MCOs and EQRO of PIHPs, PAHPs and some PCCM entities, we recommend that HHS maintain availability of enhanced match for EQR and EQR related activities for all the managed care plans subject to EQR.

**Recommendation:** Revert to the currently effective regulation that allows 75 percent federal match for EQR and EQR-related activities of PIHPs and extend the availability of that enhanced matching rate to PAHPs and PCCM entities as well.

## **F. Grievance System**

Increasing numbers of children, including children with disabling and chronic conditions, are being enrolled in Medicaid managed care plans. These plans use coverage procedures that are confusing to enrollees, take too long for them to use, and incorporate utilization controls that terminate services without appeal rights even though the child's health condition persists. Nonprofit organizations that provide legal services to low income families have seen their managed care plans establish shorter periods of authorization for approved services. The NHeLP, in particular, has had cases where children with developmental disabilities have had their ongoing care terminated at the end of a 90 day authorization period. Parents seeking to contest the termination have been told by the health plan that they cannot appeal because they already received the service; state employees have told them to forego or dismiss their complaint because the case became moot when the authorization period ended before the date of the hearing.

With that in mind, the proposed regulations make significant strides toward making managed care grievance systems a more integral part of the care management and coordination functions of Medicaid managed care. However, we do have some concerns that echo the concerns raised in the NHeLP's comments. Most notably, while we understand the desire to align Medicaid with Medicare Advantage and the commercial market to promote ease of transition between different types of coverage, the existence of constitutional notice and pre-termination hearing rights in Medicaid makes some aspect of the Medicaid grievance and appeal process unique and impossible to align. Thus, when called for, the regulations need to specifically explain how Medicaid is different. With that in mind, we support the comments provided by the NHeLP that balance the desire to align grievance and appeal processes across payers, while also consider how Medicaid is

different. In particular, we support the NHeLP comments in regard to §§438.400, 438.402, 438.404, 438.406, 438.408, 438.410, 438.414, 438.416, 438.420, 431.234, and 438.424.

## **G. Program Integrity**

### **§438.602 State Responsibilities**

We support the requirement at §438.602(g) to promote transparency by requiring posting of certain documents and data. We believe the requirement at §438.602(g)(3) should be finalized as proposed, however we recommend some changes to §438.602(g)(1) and (2).

**Recommendation:** Amend §438.602(g)(1) to require posting of the managed care contracts rather than allowing the state to make them available upon request. Similarly, amend §438.602(g)(2) to specifically require posting of certain elements under §438.604. Specifically, we recommend requiring posting of §438.604(a)(2) regarding data on the basis of which the state certifies the actuarial soundness of capitation rates, §438.604(a)(3) regarding data on the basis of which the state determines compliance with the MLR requirement, and §438.604(a)(5) regarding documentation described in §438.207(b) related to availability and accessibility of services.

If HHS is unable to require such posting, we recommend that HHS specify the timeframe by which the state must provide the information on request, such as within ten days.

## **CHIP REQUIREMENTS**

We strongly support HHS' proposals to implement section 2103(f) of the Act. CHIP has proven itself to be a successful program covering over eight million children, and we believe that this additional guidance on the applicability of managed care rules will protect beneficiaries and promote transparency by allowing states and other stakeholders to have more reliable and comprehensive information about managed care operations. We support the alignment of CHIP managed care standards with those of the Marketplace and Medicaid, but we understand that in some areas, full alignment is not practicable.

In finalizing these proposals, we believe it would be helpful for HHS to clarify the applicability of each subpart in part 457 based on delivery system, as it is not currently clear whether only those provisions in subpart L apply to CHIP or some or all of the other subparts are also applicable to managed care delivery systems. Additionally, we think HHS will need to issue subregulatory guidance regarding the changes states will need to make to update their CHIP state plans.

## **A. General Provisions**

### **§457.1201 Standard contract requirements**

We support the requirement at §457.1201(a) for states to submit CHIP managed care contracts to HHS for review and we note that neither submission nor approval is required as a condition for receipt of FFP. While we support CHIP alignment with Medicaid to the greatest extent possible, we recognize that CHIP may be treated differently in some areas due to statutory constraints and differences in program structure. HHS may want to align CHIP with Medicaid and require prior approval of managed care contracts in the future, once states are accustomed to submitting the contracts and the subsequent review processes. In the meantime, in order to promote consistent adherence to the submission requirement and to ease enforcement, we believe that contract submission should be a condition to receive FFP. We support the requirement at §457.1201(c) to include the rates that will be paid to the managed care entities in the contract submissions.

**Recommendation:** Condition FFP on timely submission of managed care contracts to HHS. In prior guidance, HHS encouraged submission at least 60 days prior to the desired effective date (SHO 09-008). We recommend HHS require submission 90 days prior to the effective date of the contract in order to be consistent with the Medicaid requirement at §438.3(a).

We support the alignment with Medicaid contract provisions, but note that at §457.1201(l) regarding additional rules for contracts with PCCMs, two of the five Medicaid requirements were not carried over. We believe HHS intended to apply paragraphs (4) and (5) under §438.3(q) regarding discrimination and disenrollment, respectively, to CHIP as well. We would support full alignment in this area.

**Recommendation:** Add paragraphs (4) and (5) from §438.3(q) to §457.1201(l) as new paragraphs (4) and (5) to fully align the CHIP PCCM contract rules with Medicaid.

We also support aligning CHIP contract provisions for PCCM entities with Medicaid at §457.1201(m), but we note that there are a few differences in the application of these requirements as proposed. We believe HHS intended to apply the same contracting rules for PCCM entities in Medicaid and CHIP, therefore, we suggest the following edits at §457.1201(m): clarify the application of paragraph (l); change the cross reference from §457.1206 to §457.1207; limit the cross reference to §457.1240(b) such that only §438.330(b)(3), §438.330(c), and §438.330(e) apply; change the cross reference from §457.1240(f) to §457.1250; and strike the final clause beginning with “...if the State’s contract...”.

**Recommendation:** Amend subsection (m) of §457.1201 to fully align with subsection (r) of §438.3.

We agree with HHS that while alignment between Medicaid and CHIP is valuable, there are instances where alignment is not practicable. We support exclusion of many of the contract provisions from §438.3, but note that some of the excluded provisions would provide valuable information about program operations and therefore encourage HHS to reconsider their application to CHIP. Specifically, we encourage HHS to consider applying

§438.3(e) regarding services that may be covered outside of the state plan if such services are covered in CHIP (we also note that we believe the preamble for this section should read “because we *do not* review rates”); §438.3(g) regarding advance directives; and paragraphs (1), (4), (5), and (6) of §438.3(s) regarding standards for coverage of outpatient drugs, utilization review, and prior authorization. Applying these provisions would provide additional information about CHIP contracts that would be useful for state and HHS oversight.

**Recommendation:** Consider applying additional provisions from §438.3 to §457.1201, specifically §438.3(e), §438.3(g), and paragraphs (1), (4), (5) and (6) of §438.3(s).

Finally, we believe that HHS will need to issue subregulatory guidance to states with a checklist for the managed care contract requirements, so that states are able to comply with these new rules as easily as possible.

#### **§457.1203 Rate development standards**

We strongly support adopting a minimum MLR in CHIP at §457.1203(c). We understand that the Medicaid MLR requirement as described in §438.4(b)(8) is a requirement in CHIP at §457.1203(c) and that the standards for calculating the MLR at §438.8 and the reporting requirements at §438.74 are applied to CHIP in §457.1205. While we are aware that §438.4 does not apply to CHIP directly, we have repeated our comments to that section here because, as HHS noted in the preamble, the CHIP proposal is the same as that proposed at §438.4(b)(7).

*We strongly agree that capitation rates for MCOs, PIHPs and PAHPs must be reviewed and approved by CMS as actuarially sound, and that approval be conditioned on meeting the requirements described in subparagraphs (b)(1-8).*

*We especially support the requirement in (b)(1) that proposed differences in capitation rates must not be based on the federal financial participation (FFP) percentage associated with the covered populations. We agree with the discussion in the preamble that such practices could lead to cost-shifting from states to the federal government, and that such differences would not be based on generally accepted actuarial principles or practices. We also support the requirement in (b)(8) that a medical loss ratio (MLR) of at least 85 percent be assumed in the capitation rate. We are concerned, however, that there is no upper limit on the MLRs assumed into capitation rates, and the only requirement is that the capitation rates overall be adequate for necessary and reasonable administrative costs. This requirement is vague and could permit some capitation rates to be set at inadequate levels, which would be reflected with MLRs approaching 100 percent (with the likely result in beneficiaries experiencing limited access to needed care). We recommend that HHS specify an appropriate upper limit on the MLRs assumed in capitation rates.*



We note that there is an error in the preamble, which should reference §438.4(b)(8) rather than §438.4(b)(7).

As with the contracting provisions, there are some provisions related to payment rates that HHS has not adopted in CHIP due to the statutory and programmatic differences between Medicaid and CHIP. We agree that the application of each provision to CHIP should be carefully considered with these differences in mind. For example, while we believe it would be highly valuable to apply all of the actuarial soundness provisions and rate development standards from §§438.4 and 438.5, we realize that there are statutory barriers that prevent such application. However, we believe that the special contract provisions related to payment under §438.6 should be a required element of the CHIP contracts, as applicable, so that the payment structures are transparent, even if the CHIP payment rates will not be certified by HHS as required for Medicaid under §438.7. Even without a mandate to meet particular actuarial soundness requirements, we believe that CHIP rates should be actuarially sound. That is, in order to be good stewards of public dollars, the rates should be calculated according to widely accepted principles of actuarial science. Additionally, we believe that HHS should collect information about CHIP rates to promote transparency.

**Recommendation:** Amend §457.1203 to require inclusion of the additional payment information as described in §438.6 in CHIP contracts, as applicable, in order to promote payment rate validity and transparency.

#### **§457.1205 Medical loss ratio**

We strongly support setting standards for how the MLR in CHIP is calculated and reported in order to make the information available and consistent. We do not have any CHIP-specific comments, but instead repeat our comments on §§438.8, 438.74 and §438.602 here for easy reference.

*We strongly support the proposed addition of a MLR as a contractual requirement for MCOs, PIHPs and PAHPs operating in Medicaid (and CHIP) beginning in 2017. This new requirement aligns Medicaid and CHIP with requirements established by the ACA for the private sector and requirements already established for Medicare Advantage plans.*

*MLRs have the potential to ensure better value for public funds used to purchase coverage for Medicaid and CHIP beneficiaries. MLRs also enhance the ability of states to assess the actuarial soundness of capitation rates and ideally promote the success of better actors in the insurance market – i.e., those with lower administrative costs who are devoting higher levels of premium funds to paying for incurred claims.*

*A recent study by researchers at the Urban Institute speaks to the public policy value of having an MLR. This analysis found that “The ACA’s minimum MLR rule had a direct effect on insurer behavior that increased value for consumers and increased efficiency in the individual and small group markets.”<sup>5</sup>*

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<sup>5</sup> Clemens-Cope et al, “Health Insurer Responses to Medical Loss Ratio Regulation: Increased Efficiency and Value to Consumers” Robert Wood Johnson Foundation, May 2015.

*In order to maximize the potential value of an MLR in the Medicaid and CHIP programs, we offer the following specific comments:*

***Recommendation:*** *Delete language at 438.8 implying that the MLR is optional for states: We support the requirement for states to use the MLRs and MLR history for assessing actuarial soundness and setting payment rates under §438.4. We agree that there should be a uniform minimum MLR of at least 85 percent and urge you to delete language at 438.8(c) that begins “If a State elects to mandate a minimum MLR...” This language creates the impression that the minimum threshold of 85 percent for the MLR is optional and contradicts the intent of the regulation.*

***Recommendation:*** *In order to align Medicaid’s MLR with the MLR in the private market, and in order to ensure that the full public policy value of an MLR is realized, we recommend that States collect remittances from each MCO, PIHP and PAHP that fails to meet the minimum MLR.*

*An enforceable MLR of 85 percent is a threshold that plans should not have difficulty meeting. According to the Kaiser Family Foundation, in the vast majority of States for which data were available, the average Medicaid managed care MLRs were 85 percent or higher. Moreover, as the preamble states, Milliman data state that the average Medicaid managed care MLR from 2011 to 2013 was 87 percent.*

*Given that the MLR is a new requirement for Medicaid, a phase-in may be appropriate. At a minimum, however, all States and MCOs, PIHPs and PAHPs should be subject to an annual minimum MLR requirement of 85 percent enforceable through remittances. There also may be a need to ensure that remittances do not have an adverse impact on particular types of MCOs such as safety-net plans. HHS should carefully evaluate, as it implements an annual enforceable MLR requirement, whether certain types of MCOs, PIHPs and PAHPs are more likely to experience unexpected year-to-year MLR fluctuations and if so, consider potential adjustments to take such fluctuations into account in its MLR requirement.*

***Recommendation:*** *Establish a uniform MLR reporting year. We are concerned that allowing each State to set the MLR reporting year (which could be the contract year, calendar year, State fiscal year, or Federal fiscal year but must be consistent with the rating year), would make it impossible to make comparisons across States and particularly across plans offered by the same issuer but in different States. Again this flexibility would undermine one of the key values of an MLR, which stems from its use as a tool to drive improved decision-making in the pursuit of greater value by consumers and states.*

***Recommendation:*** *Strengthen public reporting and transparency provisions. The value of an MLR is greatly diminished if it is not publicly reported and routinely audited. For consumers choosing plans, as well as for researchers, stakeholders and legislators, a publicly reported MLR that is consistently defined and reported by all plans in a timely way is an important step forward to driving better quality of care in the Medicaid program. We understand that CMS intends for MLRs to be reported in a timely way but we believe these requirements must be strengthened in the final rule. The current language in*

our judgment could result in states reporting the information to CMS but not necessarily to the public.

Specifically, we recommend amending §438.74(a) to include the following language:

*State reporting requirement. (1) The State must annually submit to CMS a summary description of the report(s), **and the reports themselves**, received from the MCO(s), PIHP(s), and PAHP(s) under contract with the State under § 438.8(k) with the actuarial certification described in §438.7. **The reports and summaries must also be made publically available by HHS, including by posting on an internet website.***

**Recommendation:** We recommend that HHS modify the regulation to require that the MLR requirements applying to a MCO, PIHP, and PAHP apply to the totality of care provided by that contractor, regardless of any subcontracts that are in effect or entered into. In practice, this means that managed care plans should not be allowed to wholesale include the expenses paid to a subcontractor in the numerator, without adjusting that expense for the administrative costs of the subcontractor. If a contractor provides only services, it could all count in the numerator (incurred claims), however if a contractor only performs administrative functions, it should not count in the numerator. Meanwhile, if the contractor performs mixed functions (both services and administration), the plan should attribute to the MLR the respective portions of the contract for services and administration. For example, if a subcontractor is paid \$10 million to provide dental services, but that subcontractor itself operated at a 70% MLR, the managed care plan should include \$7 million (and not \$10 million) for the dental services in the numerator of the managed care plan's MLR calculation.

**Recommendation:** At §438.602 regarding state responsibilities, we recommend that subsection (g) on transparency be amended to require the state post on an internet website the summaries (but not the reports) that are submitted to HHS to comply with the above reporting requirement (i.e., delete the language for states to make this information available upon request). We also recommend that states be required to post on an internet website a comprehensive and easily accessible list of Medicaid and CHIP plans and their MLRs. See comments on §438.602.

#### **§457.1206 Non-emergency medical transportation PAHPs**

We support aligning the Medicaid and CHIP rules non-emergency medical transportation (NEMT) PAHPs at §457.1206, however we note that there are a few differences between §457.1206(b) and §438.9(b), other than those identified in the preamble related to advance directives and long-term services and supports (LTSS), that we think HHS should consider.

Regarding the proposal to exclude the advance directives and LTSS in §457.1206(b)(1), we understand that these provisions may have limited applicability to the CHIP population, but we believe there are some CHIP beneficiaries for whom these provisions would apply. For

example, advance directives may be applicable for pregnant women and beneficiaries over 18 years old. Similarly, some CHIP beneficiaries may rely on LTSS for mental health, substance use, and other chronic conditions. We encourage HHS to carefully consider the applicability of these services to the CHIP population. We understand that the burden associated with compliance may outweigh the benefit if the applicability is narrow, but believe that additional consideration is warranted. Also in §457.1206(b)(1), we note that CHIP includes a requirement at subparagraph (ii) regarding audited financial reports that we did not see in Medicaid. We support full alignment for NEMT PAHPs and believe that inclusion of an audited financial report is valuable; therefore we suggest adding a similar requirement to Medicaid at §438.9(b)(1).

**Recommendation:** Consider adding advance directives and LTSS as new subparagraphs of §457.1206(b)(1) to align with Medicaid. Consider adding a requirement regarding financial reports to Medicaid NEMT PAHPs at §438.9(b)(1).

In paragraph (4), the regulatory text indicates that HHS intends to apply the provisions against provider discrimination to CHIP managed care generally and to NEMT PAHPs. Medicaid describes the provider discrimination rule at §438.12 and applies it to NEMT PAHPs at §438.9(b)(4). We believe that HHS intended to fully align these provisions, and to that end, we recommend that HHS add a new provision to subpart L of part 457 with respect to provider discrimination generally and include that new reference to NEMT PAHPs at §457.1206(b)(4). The reference currently at §457.1206(b)(4) relates to contracts involving Indians, which we believe is an error.

**Recommendation:** Apply §438.12 to CHIP and amend the cross reference at paragraph (4) of §457.1206(b) to reference the new provision against provider discrimination.

Similarly, the provisions in paragraph (7) of §457.1206(b) are not fully aligned with Medicaid, which we believe is the intent. Therefore, we recommend that HHS revise the cross references related to §457.1233 to include §457.1233(a), (b) and (d) instead of §457.1233(a)-(c). The Medicaid requirements also include §438.224 regarding confidentiality, and while CHIP has existing regulations governing confidentiality at §457.1110, we did not identify a provision in subpart L of part 457 which would apply this confidentiality provision to managed care. We believe HHS intended full alignment, and therefore suggest that HHS add a new provision to subpart L of part 457 applying §457.1110 to managed care and include a cross reference to that new section in §457.1206(b)(7) for application to NEMT PAHPs.

**Recommendation:** Align the provisions of §457.1206(b)(7) with those in §438.9(b)(7) by amending the reference to §457.1233(a)-(c) to §457.1233(a), (b), and (d) and adding a new provision to subpart L of part 457 regarding confidentiality, like §457.1110, and including a cross reference to that section in §457.1206(b)(7) for application to NEMT PAHPs.

We also note that there is an error in paragraph (1) of §457.1206; the cross reference to §457.1202 should be to §457.1201.

### **§457.1207 Information requirements**

While we do not have any recommendations specific to the application of §438.10 to CHIP at §457.1207, we repeat our comments regarding §438.10 here for ease of reference.

*Overall, we applaud the administration's effort to boost information requirements to assure that consumers receive all of the information they need to make informed plan selections and are able to access the assistance and services they need.*

#### *§438.10(a) Definitions*

*We believe the definition of "prevalent" should be clarified even further to ensure that the intent of standardizing the availability of written translations of non-English languages is clear. Additionally, we recommend that the requirement be based on an entity's service area rather than statewide or county data.*

***Recommendation:*** *Prevalent means a non-English language determined to be spoken by a significant number or percentage of 1,000 or 5 percent of potential enrollees or enrollees in the entity's service area that are limited English proficient and consistent with standards used by the Office for Civil Rights in enforcing anti-discrimination provisions in Title VI of the Civil Rights Act of 1964 and Section 1557 of the Affordable Care Act. If a covered entity conducts targeted marketing, outreach or other activities directed at a specific non-English language group, that covered entity must provide all materials specified in subsection (d)(3) in that language as well as other materials related to the type of marketing, outreach or other activities being conducted.*

*We also support the recommendation of the National Health Law Program (NHeLP) to add a definition of competent healthcare interpreter, competent translation services, and competent healthcare translator.*

#### *§438.10(b) Applicability*

*We support aligning applicability across all types of managed care.*

#### *§438.10(c) Basic rules*

*We applaud the requirement to bring transparency to the forefront by requiring that a broad array of content as specified in this regulation be provided to enrollees and potential enrollees (§438.10(c)(3)). We agree that certain types of information are more useful for enrollees, potential enrollees or other stakeholders. However, the proposed rule at times distinguishes between enrollees and potential enrollees. This distinction should be for targeting information and outreach, not to limit whom has access to the information. Accordingly, we recommend that HHS strengthen and broaden the rule by requiring that the state website must make all information provided to enrollees and potential enrollees publicly available.*

***Recommendation:*** *Amend §438.10(c)(3) as follows: The state must operate a website that provides to the general public the content specified in paragraphs (e) through (g) and (h) of this section, §438.68(e), §438.74,*

*§438.364(b)(2), and §438.602(g), either directly or by linking to individual MCO, PIHP, PAHP or PCCM entity websites. **The state website should have a dedicated section for consumer information that includes all of the information that must be posted as detailed in Part 438.***

*We believe that establishing standard definitions for managed care terminology will help enrollees and potential enrollees understand what services they are able to receive, the types of providers within their available network, and provide basic understanding of managed care as a whole (§438.10(c)(4)(ii)). Such an understanding will help enrollees make informed choices about their health care; however, allowing states to develop their own definitions for the terminology could present problems. States may develop definitions that are different from other types of healthcare plans, which could create confusion for enrollees who may be familiar with a certain term but understand it to mean something different than the state's definition. Additionally, states could develop different definitions from one another. If someone enrolled in a managed care plan in Florida moves to Georgia, the varying definitions could cause confusion for this individual. State-developed definitions may also be confusing for enrollees, so they may not understand the services and benefits they are entitled to receive. We also believe that it will be more cost-effective for states to adopt standard terms rather than duplicitous creation of such terms.*

*To promote health literacy and reduce state costs, we recommend that HHS develop the definitions for the required terminology with state and stakeholder input, so there will be standardization across all plans in every state. If HHS is unable to create standard definitions for managed care terminology, then HHS should develop model definitions for states to adopt or use as a starting point for developing their own definitions. Such standard definitions should be consumer-tested before they are finalized.*

**Recommendation:** *HHS should develop standard definitions for managed care terminology at §438.10(c)(4)(ii), or minimally develop model definitions through sub-regulatory guidance for states to use.*

*The NPRM requires that enrollee information provided electronically must meet accessibility and other standards for electronic information (§438.10(c)(6)). However, the regulatory language is confusing and could be construed as though providing information in this format is optional. HHS should require states to provide this information electronically, and in compliance with the standards in the rule.*

*Additionally, while we support the requirement at §438.10(c)(6)(ii) to display the information in a prominent and readily accessible place, we believe this requirement can be strengthened by the language we have suggested above under §438.10(c)(3). Many state websites are difficult for consumers to navigate, with information moving to new places frequently. Therefore, we believe that states should be required to section specific to consumer information so that all such information is in one place.*

**Recommendation:** *HHS should amend §438.10(c)(6) to read: (6) **All** Enrollee information required in this section ~~may not~~ **must** be provided electronically by the State, MCO, PIHP, PAHP, PCCM or PCCM entity ~~unless~~, **and must meet** all of the following:*

*It is unclear what the intended "mechanism" might be to help enrollees and potential enrollees (§438.10(c)(7)). A mechanism could take many forms, such as a Frequently*

*Asked Question document (FAQ) or Fact Sheet, which will likely be insufficient in assisting enrollees and potential enrollees in understanding the requirements and benefits of the plan. Establishing a structure to help enrollees and potential enrollees understand the requirements and benefits of the plan is an essential way to ensure that enrollees are aware of available services. Considering the overall scheme §438.10, a structure is needed to make sure enrollees and potential enrollees are able to easily navigate their managed care plan and truly help individuals access their care. To ensure that enrollees and potential enrollees receive the help they need, we recommend that HHS replace “mechanism” with “system.” To make sure that plans are providing the assistance described in this section, a mechanism is unlikely to provide the same help that a full-scale system would provide, and such a system is necessary to actually help enrollees and potential enrollees understand their plan. To further the goal of increasing information access, we also recommend that HHS issue additional guidance to provide plans with a better understanding of what type of system is needed, even if the term mechanism is used. This will help managed care plans develop a structure that provides the necessary support to achieve the desired goals.*

**Recommendation:** Amend §438.10(c)(7) as follows: Each MCO, PIHP, PAHP, and PCCM entity must have in place a ~~mechanism~~ **system** to help enrollees and potential enrollees understand the requirements and benefits of the plan. HHS should issue additional guidance to plans on system requirements.

#### *§438.10(d) Language and Format*

*We generally support the requirements in subsection (d) with certain modifications and clarifications.*

*Paragraph (1) could be interpreted to leave the methodology for determining prevalent up to the state.*

**Recommendation:** Amend subsection §438.10(d) as follows: (1) ~~Establish~~ Utilize the methodology for identifying the prevalent non-English languages spoken by enrollees and potential enrollees throughout the State, and in each MCO, PIHP, PAHP, or PCCM entity service area **developed under subsection (a).**

*Paragraph (2) implies that oral interpretation only has to be provided in prevalent languages, which is inconsistent with other parts of this section (e.g., paragraph (5)). We do not think this is the intent and, therefore, recommend rewording this paragraph. We also suggest that HHS require a minimum number of taglines be included on notices, and align with requirements in other coverage programs. Specifically, 45 CFR §155.205, known as the payment and parameters rule, requires private insurers to include taglines in at least 15 languages.*

**Recommendation:** Amend subsection §438.10(d) as follows: (2) Make available **competent oral information in all languages and** written information in each prevalent non-English language. All written materials for potential enrollees must include **prominent taglines in each prevalent non-English language at least 15 non-English languages** as well as large print explaining the availability of written translation ~~or~~ **and** oral interpretation...

*Paragraph (3) lists a number of “vital” documents to which this subsection applies, but does not specifically include denial and termination notices.*

**Recommendation:** Amend subsection (d) as follows: (3) Require each MCO, PIHP, PAHP, and PCCM entity to make its written materials, including at a minimum, provider directories, member handbooks, appeal and grievance notices, **denial and termination notices**, and other notices that are critical to obtaining services...

There is widespread misunderstanding about the required knowledge, skills and abilities needed to be a competent healthcare interpreter, which can lead to a lack of competency in practice. It is important to maintain consistency in terminology, therefore we suggest changing “skilled interpreter” to “competent interpreter.” We also suggest defining “competent” interpreter. As a reference, the NHeLP and the National Council on Interpreting in Health Care and the American Translators Association, [What’s in a Word? A Guide to Understanding Interpreting and Translation in Health Care](#). The Guide explains the differences between interpreting and translation and the knowledge, skills and abilities needed of both. This can serve as a reference for states and managed care entities seeking to comply with requirements to provide competent and accurate interpreting and translation.

**Recommendation:** Amend subsection §438.10(d) as follows: (4) Make **competent** interpretation services available to each potential enrollee and require such MCO, PIHP, PAHP and PCCM entity to make those services available free of charge to each enrollee. This includes oral interpretation and the use of auxiliary aids such as TTY/TDY and American Sign Language. Oral interpretation requirements apply to all non-English languages and not just those identified as prevalent.

We support the inclusion of definitions relating to competent interpretation recommended by the NHeLP. We also recognize that other sections and subsections of the NPRM address language access and support the integration of “competent” interpretation services as recommended by disability and legal experts in other parts of this regulation.

At §438.10(d)(6), we recommend adding a clarification to subparagraph (ii) that cross-references back to the requirement for a large print tagline. While we recognize (ii) is a more general requirement, we do not want any possibility of confusion with regard to the requirements for a large print tagline on all documents.

**Recommendation:** Amend §438.10(d)(6)(ii) as follows: Use a font size no smaller than 12 point, **except as required in subparagraph (d)(3)(i)**.

438.10(e) Information for potential enrollees

Providing potential enrollees with information about their benefits and services before choosing to enroll in a managed care program will enable these individuals to make an informed decision about their healthcare plan. When individuals are given more information about healthcare options, they will be better able to make the choice best for them.

438.10(f) Information for all enrollees

As noted previously, we believe all information should be available to all potential enrollees, enrollees and the public. However, §438.10(f)(3) requires that managed care entities only make information about physician incentive programs available upon request. Transparency is important for enrollees to fully understand their managed care and physician choices. To assist enrollees in understanding the care they receive,



*we recommend managed care plans must always provide information regarding physician incentive plans, regardless of whether an enrollee requests this information.*

**Recommendation:** *The state should post physician incentive programs on its website (§438.10(c)(3)) or require managed care plans to make such information available to potential enrollees, enrollees and the public without requiring that the information be requested.*

*We also recommend that the regulations include a requirement that plans inform enrollees that they can request that communications containing medical information be communicated to the enrollee at a specific mail or email address or telephone number, as designated by that enrollee. Allowing alternate and specifically designated contact information is important for a variety of enrollees. For example, enrollees who may receive certain services they do not want their parents knowing about (e.g., family planning services or supplies) and other enrollees who might be seeking "sensitive" services (e.g., victims of intimate partner violence, etc.).*

**Recommendation:** *Amend subsection (f) to add new paragraph (4): **The State and the MCO, PIHP, PAHP and, when appropriate, the PCCM entity must notify all enrollees of their right to designate a mail or an email address or telephone number to receive plan communications regarding medical information if the enrollee does not want the information being sent to the primary address designated on the application. Notice to the enrollee must clearly explain how the enrollee can make a request and provide a form or telephone number to call to complete the request.***

*§438.10(g) Information for enrollees of MCOs, PIHPs, PAHPs and PCCM entities – Enrollee handbook*

*Enrollees need information about how to access services quickly after they enroll. Accordingly, we recommend defining “within a reasonable time” during which a managed care entity must provide each enrollee with an enrollee handbook at §438.10(g)(1).*

**Recommendation:** *Amend subsection §438.10(g) as follows: (1) Each MCO, PIHP, PAHP and PCCM entity must provide each enrollee an enrollee handbook, ~~within a reasonable time~~ **5 days** after receiving notice of the beneficiary’s enrollment, which serves a similar function as the summary of benefits and coverage described in 45 CFR §147.200(a).*

*We believe that consumers will benefit from standardization of enrollee handbook formats and content for many of the same reasons cited in our recommendation for standard managed care terms at §438.10(c)(4)(ii). Accordingly, we urge HHS to develop model or template member handbooks. This will ensure uniformity across managed care plans within the state and across the country. If HHS cannot create models for states to use, a basic template will also help to create more uniformity and less confusion. To ensure that these informational materials are easy to understand and achieve the desired goal of informing enrollees, state or HHS materials should be subject to consumer testing. We also believe that model or template handbooks will save the time and expense of duplicating this effort across 50 states.*

**Recommendation:** *HHS should develop model or template enrollee handbooks. At §438.10(g)(2)(xi), which contains grievance, appeal and fair hearing procedures and timeframes, we recommend including information about the availability of*

language services and accommodations. Most of the discussion of information requirements applies to plan activities and while grievances and appeals may be internal, to the extent that they may be delegated to a third party, and particular in the case of fair hearings which would be conducted by an entity external to the MCO entity, requirements for language services and accommodations for individuals with disabilities should be specified.

**Recommendation:** Amend §438.10(g)(2)(xi) to add a new (F) as follows: **The availability of free, competent oral interpretation and written translation of materials for individuals who are limited English proficient and free auxiliary aids and services for individuals with disabilities.**

We appreciate the inclusion of information about how to access auxiliary aids and services at §438.10(g)(2)(xiii). We suggest similar language to inform about accessing language services so that the managed care entity must not only provide language services but also inform enrollees about their availability. We recommend amending subparagraph (xiii), but HHS could also insert a new subparagraph specifically about language services.

**Recommendation:** Amend subparagraph (xiii) of §438.10(g)(2) as follows: How to access auxiliary aids and services **and oral translation and written materials**, including additional information in alternative formats or languages.

Given that the enrollee handbook is an excellent resource to aid enrollees in understanding their benefits and how to most effectively use a managed care program, we recommend requiring additional content at §438.10(g)(2) as follows: The right to disenroll. Ensuring that enrollees understand their rights is essential to creating a streamlined and efficient healthcare delivery system, and we are appreciative of the increased requirements governing information for enrollees about their rights. For those currently enrolled, we recommend adding information to the enrollee handbook regarding the enrollee's right to disenroll. This information should be provided in addition to the notification the state provides. The enrollee handbook must also provide this information consistent with state requirements, where the plan must explain the disenrollment process and identify available alternatives. If the State limits disenrollment to a certain time frame, the enrollee handbook should specify that timeframe. This inclusion will inform enrollees that they have the right to leave the plan and evaluate their additional healthcare options.

**Recommendation:** Require that the enrollee handbook provide information regarding the enrollee's right to disenroll. This information should meet the same state requirements by providing information about the disenrollment process, healthcare alternatives, and timeframe restrictions.

Family planning services. Freedom of choice for family planning providers, which ensures that women may choose a provider that best suits their needs, is protected in the Medicaid statute. We are therefore concerned that the regulatory language requires plans to explain "the extent to which" enrollees can obtain family planning services out-of-network. In order to ensure that managed care plans do not misinform women about their ability to go out-of-network for family planning, or attempt to limit a woman's family planning provider options, HHS should clarify that plans must fully inform women about these rights.

**Recommendation:** *The enrollee handbook should clearly state there are no limits on a woman's freedom of choice for family planning providers.*  
Network adequacy standards. *Given that HHS has proposed that states set network adequacy standards based on time and distance, which is something that consumers can readily understand, we recommend that these standards be a required element of the enrollee handbook. Doing so provides another opportunity for states to validate that plans are meeting the standards.*

**Recommendation:** *The enrollee handbook should include the state's network adequacy standards and what steps enrollees should take when they are not able to access services in a manner consistent with the standards.*

Consumer testing. *As healthcare terminology is confusing to many people, we recommend that the entire enrollee handbook be subject to consumer testing. The enrollee handbook is a resource for enrollees to understand how to effectively use their managed care program. To make certain the handbook serves this function, consumer testing is necessary to ensure enrollees are able to understand the information provided to them in the handbook.*

**Recommendation:** *The enrollee handbook should be subject to consumer testing to ensure enrollees understand the content of the handbook.*

*At §438.10(g)(3), it is not clear how the requirements of paragraph (g)(3) interact with paragraph (c)(6). Paragraph (c)(6) outlines when information may be provided electronically. However, subparagraphs (g)(3)(ii) and (iii) do not refer back to (c)(6).*

**Recommendation:** *Amend subsection (g)(3)(ii) and (iii) as follows:*

*(ii) Provides the information by email, **in compliance with subsection (c)(6)**, after obtaining the enrollee's agreement to receive the information by email;*

*(iii) Posts the information on the website of the MCO, PIHP, PAHP, or PCCM entity, **in compliance with subsection (c)(6)**, and advises the enrollee that the information is available on the Internet, **how to request a paper copy**, and includes the applicable Internet address...*

*Additionally, with regard to subparagraph (g)(3)(iii), we strongly support the requirement for plans that wish to provide information solely on its website to be required to provide notice of the available information to the enrollee in paper or electronic form. Many low-income consumers may not have ready access to a computer. Further, individuals who are LEP may not have the ability to understand this information. We also suggest that if the entity wishes to advise the enrollee in electronic form, it must first obtain the enrollee's consent, similar to subparagraph (g)(3)(ii).*

*§438.10(h) Information for all enrollees of MCOs, PIHPS, PAHPs and PCCM entities:  
Provider Directory*

*We greatly appreciate the inclusion of a provider's cultural and linguistic capabilities in the provider directory. However, we are concerned about the self-identification of a provider's (or his/her staff's) language. Some providers may have some proficiency but are not completely bilingual, particularly when it comes to specialized healthcare terminology. They may be able to greet a person who is LEP in his or her language but not have sufficient language skills to take a health history or provide healthcare services in that language. Thus, a provider who is not sufficiently bilingual to provide*

services directly in a non-English language should not be included in a provider directory regarding language skills.

We recommend clarifying that for a provider's linguistic skills to be included in a provider directory, the provider must have demonstrated language proficiency in English (for non-native English speakers) and the non-English language, including specialized terminology, which can be demonstrated by taking a language proficiency examination. As a note, we reference "sign language interpreter" below rather than "American Sign Language" in recognition that some enrollees may need assistance in another country's sign language.

**Recommendation:** Amend §438.10(h)(1)(vii) as follows: The provider's cultural and linguistic skills, including languages spoken by the provider or by skilled medical interpreter at the provider's office. **To include a provider's language skills in the directory, the provider must demonstrate he/she:**

**(A) Is proficient and able to communicate all healthcare information accurately in the non-English language or sign language for which the provider will provide services in a non-English language or sign language; and**

**(B) Possesses proficiency in the non-English language or sign language for which services will be provided including knowledge of:**

**(1) Specialized healthcare terms and concepts in both languages; and**

**(2) Any particularized vocabulary and phraseology likely to be used by the limited English proficient person or person needing a sign language interpreter, such as regional usages of terms;**

**If a provider only has conversational capabilities in a non-English language or sign language, the provider may not list that language in the provider directory.**

We appreciate inclusion of the term "skilled medical interpreter" as a method of identifying providers who can offer language services in their offices. However, as noted above, we would recommend changing "skilled" to "competent."

Given the overall lack of understanding of the knowledge, skills and abilities required of healthcare interpreters throughout the healthcare arena, we recommend defining what a competent interpreter is so that if a provider identifies as having a "competent interpreter," enrollees will be able to rely on that identification and not select a provider who really does not provide sufficient language services.

As compared to the above section about including language skills in a provider directory and using the broad term "sign language," in our recommendations below we specifically reference "American Sign Language" since that is the only available certification for interpreters working with individuals who are deaf or hard of hearing.

**Recommendation:** In subsection (h)(vii), change "skilled" to "competent". If a definition of "competent medical interpreter" is not added to subsection (a), add a definition as follows to clarify subsection (h)(1)(vii): **A competent medical interpreter for a non-English language is either:**

**(A) An individual who has been certified by a national certifying body as a healthcare interpreter; or**

**(B) An individual who:**

**(1) Is over the age of eighteen;**

- (2) Is proficient and able to communicate information accurately in both English and in the language for which interpreting is needed;**
- (3) Possesses, to the extent necessary for communication, knowledge in English and in the language for which interpreting is needed of:**
- (i) Specialized healthcare terms and concepts; and**
  - (ii) Any particularized vocabulary and phraseology used by the limited English proficient person or healthcare provider, such as regional usages of terms;**
- (4) Attests to comply with the National Code of Ethics and National Standards of Practice as published by the National Council on Interpreting in Health Care;**
- (5) Attests to adhere to the role of an interpreter as defined by the National Code of Ethics and National Standards of Practice as published by the National Council on Interpreting in Health Care; and**
- (6) Attests to adhere to HIPAA requirements to the same extent as the healthcare provider for whom interpreting is provided.**
- A competent medical interpreter for American Sign Language is an individual who has been certified by a national or state certifying body as an interpreter for American Sign Language.**

*We are also concerned about the quality of translation of written materials. We believe covered entities must take appropriate steps to ensure that required translations are competent and not done through machine translation which does not produce competent translations.*

*We appreciate the recognition that the accessibility of a provider is important information to be included in the provider directory. While we support the features listed of the offices, exam room(s), and equipment, we are concerned that this section does not provide enough information about important aspects of accessibility for individuals with disabilities. As indicated in the proposed regulations, there are different aspects of physical accessibility that are important, including the provider offices and the available equipment. The minimum requirements for physical accessibility are set forth in the Americans with Disabilities Act Standards for Accessible Design and the related regulations. Accessible medical diagnostic equipment standards are being developed pursuant to the ACA's recognition of the issue in amending Section 510 of the Rehabilitation Act. Based on the presumption that providers are supposed to already be meeting the minimum standards of accessibility, the information that would be valuable in the provider directory is whether or not the provider is more accessible than minimally required in these clear guidelines. We also suggest that providers be provided an opportunity to indicate how they exceed the guidelines, such as in physical structure or equipment, or the types of disabilities they are specifically designed to accommodate. We are also recommending changing "office" to "office building" because a provider's office may be accessible but not be in a building or have an pathway that is accessible. We believe the term office may be too limiting and that the term office building is sufficiently broad to address this issue.*

*Further, we are concerned that the proposed regulation only addresses physical disabilities. People with disabilities experience barriers to healthcare that are often*

not about physical access, but about failures to accommodate for other types of disabilities. We believe that a provider directory should provide information about access generally so as to not discriminate amongst different types of disabilities in the information it provides. While there are not structurally measurable standards for non-physical disabilities, the provider directory should allow a provider to indicate other areas in which they have enhanced accessibility or commonly provide certain accommodations, such as sedation dentistry often used for people with intellectual disabilities or mental health diagnoses, or on-site American Sign Language interpretation.

**Recommendation:** Amend section (h)(viii) as follows: *Whether the provider's office/facility is accessible for people with physical disabilities exceeds physical accessibility requirements, including offices buildings, exam room(s), and equipment, and/or the provider has other enhanced features for people with disabilities.*

§438.10(i) Information for all enrollees of MCOs, PIHPs, PAHPs and PCCM entities: Formulary

We strongly support HHS' proposal to increase formulary transparency so that consumers can select the Medicaid managed care plan that best meets their individual health care needs. We agree that requiring plans to submit formulary information in a machine-readable format will facilitate search tools that allow potential enrollees and others to search across plans. Given the frequent changes in plan formularies, we urge HHS to specify how often plans must update formulary information. Additionally, it is important that formularies be available to potential enrollees in addition to enrollees.

**Recommendation:** Amend §438.10(i) as follows: *Information for all potential enrollees and enrollees of MCOs, PIHPs, PAHPs and PCCM entities: Formulary. Each MCO, PIHP, PAHP, and when appropriate, PCCM entity, must make available in electronic or paper form, the following information about its formulary:*

**Recommendation:** *Add a new paragraph (4) to §438.10(i) setting standards for updating the formulary as follows: (4) Information included in a paper formulary must be updated at least monthly and electronic formularies must be updated no later than 3 business days after the MCO, PIHP, PAHP or PCCM entity revises the formulary.*

With respect to §438.10(i)(2), we recognize that the practice of prescription drug tiering, including specialty drug tiers, is provided for in the Medicare Part D prescription drug benefit, and is common practice for private health plans including Qualified Health Plans (QHPs) available through the Marketplaces. However, formulary tiering by cost in Medicaid is quite limited. Federal law allows only two cost sharing levels based on income and only two tiers for prescription drugs – preferred and non-preferred. Moreover, the list distinguishing preferred and non-preferred drugs is determined by the state and would have to be consistently applied across all managed care plans in the state. See 42 C.F.R. §447.51. A Medicaid enrollee's income determines the applicable level of cost sharing, with some populations and services exempt.

Conceivably, Medicaid managed care plans could develop other types of prescription drug tiering, such as subjecting certain tiers to utilization management. Therefore, we

*recommend that HHS require plans to provide formulary information on prior authorization and other utilization management criteria, if applicable, to facilitate plan selection.*

*In addition we urge HHS to make an exceptions process easily accessible, and ensure that plans send adequate notice and explanation to beneficiaries regarding access to non-preferred medications at preferred drug cost-sharing, as well as emergency access to medication, and information on preferred and non-preferred medications. Finally, HHS should ensure that any such tiering structures comply with the rules regarding coverage and authorization of services at §438.210 and must be explained to enrollees and potential enrollees.*

***Recommendation:*** *Revise §438.10(i)(2) by adding subparagraphs (i)-(v) as follows: (2) What tier each medication is on. **MCOs, PIHPs, PAHPs, and, when appropriate, PCCM entities, shall:***

- (i) present prescription drug cost-sharing reflecting tiering by income and by preferred/non-preferred drugs as described in 42 C.F.R. §447.53;***
- (ii) provide information on prior authorization requirements or other utilization management criteria, if applicable;***
- (iii) make the exceptions process required under 42 C.F.R. §483.3(s)(7) easily accessible;***
- (iv) provide information on emergency prescription drug coverage and the availability of a 72 hour supply required under 42 C.F.R. §483.3(s)(6) and section 1927(d)(5) of the Act; and***
- (v) provide adequate notice and explanation to beneficiaries regarding access to non-preferred medications at preferred drug cost-sharing.***

## **B. State Responsibilities**

### **§457.1210 Managed care enrollment**

We support aligning the default enrollment process standards with Medicaid at §457.1210. We also recognize the challenge in interpreting whether the statute intended to require a default enrollment process in CHIP, and if so, how such a requirement could be reasonably implemented. We suggest that HHS finalize the rule as proposed, that is, with an optional CHIP default enrollment process but aligned default enrollment process standards. In the future, it would be useful to have additional information about state enrollment processes in order to develop more uniform requirements that take the statutory and programmatic differences about CHIP into account.

**Recommendation:** HHS should collect additional information about CHIP enrollment processes in order to determine how to best achieve the alignment and modernization goals of this regulation.

### **§457.1216 Continued services to enrollees**

We support the requirements at §457.1216 to align with §438.62 of this chapter. We do not have CHIP-specific requirements, but have included our comments to §438.62 below for easy reference.

*We commend HHS for expanding this section to add specific requirements aimed at ensuring that Medicaid beneficiaries have access to services during times of transition. We strongly support HHS' goal of maintaining existing provider relationships during times of transition, and we agree that these protections are needed for all enrollees, not just those in rural areas as currently provided for in §438.62.*

*We are concerned, however, that the proposed regulatory language in subsection (b)(1) will not fully achieve HHS' goal of ensuring continuity of care for enrollees during times of transition. In particular, we are concerned that the proposed language will only ensure continuity of care with an existing provider when a person moves "from FFS to a MCO, PIHP, PAHP, PCCM or PCCM entity or transition from one MCO, PIHP, PAHP, PCCM or PCCM entity to another." We believe there are other times of transition when a person may need to continue care with an existing provider that should be addressed by these regulations, including moves into a MCO, PIHP, PAHP, PCCM or PCCM entity from another insurance affordability program or private insurance; from an MCO, PIHP, PAHP, PCCM or PCCM entity to FFS; and when a provider leaves the enrollee's MCO, PIHP, PAHP, PCCM or PCCM entity.*

*In addition, we are extremely concerned that the proposed language defining the circumstances when an enrollee is eligible for continuity of care is too narrow. The proposed language would only permit enrollees to continue seeing an existing provider when lack of continuity would cause enrollee to "suffer serious detriment to their health or be at risk of hospitalization or institutionalization." We are concerned that this language would force enrollees to change providers in many situations that would not necessarily rise to the level of a serious health detriment or risk of hospitalization, but where continuity of care is enormously important to avoid unnecessary gaps in treatment or to ensure that an enrollee has appropriate access to time-sensitive services. We urge HHS to amend the criteria for when a state must require plans to offer continued access to out-of-network providers, as described below.*

***Recommendation:*** Amend §438.62(b) as follows: The state must have in effect a transition of care policy to ensure continued access to services during a transition from FFS to a MCO, PIHP, PAHP, PCCM, or PCCM entity ~~or~~; transition from one MCO, PIHP, PAHP, PCCM, or PCCM entity to another; **transition into a MCO, PIHP, PAHP, PCCM or PCCM entity from another insurance affordability program or private insurance; transition from an MCO, PIHP, PAHP, PCCM or PCCM entity to FFS; and when a provider leaves the enrollee's MCO, PIHP, PAHP, PCCM or PCCM entity. The transition of care policy must provide for continued access to services when an enrollee, in the absence of continued services, would suffer serious detriment to their health or be at risk of hospitalization or institutionalization is completing a course of treatment, has a scheduled procedure within 60 days of the transition, is receiving care for a terminal illness, is receiving pregnancy or post-partum care, or the state determines that other circumstances warrant continued access.**



*We commend HHS for setting forth the criteria states must consider in developing a plan to avoid disruptions in care during times of transition. We appreciate that HHS will require states to ensure that the scope of services is not reduced during a transition, and that HHS will require states to ensure that enrollees can continue to see their current providers for a period of time during a transition.*

*We suggest that HHS amend this section to add specific language to ensure that consumers are not subjected to additional prior authorization criteria or barriers to care when they experience transitions. Too often, consumers must repeat prior authorization for a drug or assessment for a treatment that has already been approved by FFS or their prior plan when they transition, which creates delays to care. We believe HHS' intent is that consumers should not face these kinds of barriers to care during transitions and we therefore suggest specific language to avoid confusion. In addition, we recommend that HHS set a minimum period of time for which consumers may have continued access to their current providers. At a minimum, enrollees who are engaged in a course of treatment or who have a scheduled procedure should be allowed to see their current provider until the treatment or procedure and any necessary follow-up are complete. Enrollees who are pregnant or post-partum should be allowed to complete their prenatal and post-partum care with their current provider. Enrollees who are being treated for a terminal illness should be permitted to see their current providers for the duration of the illness.*

***Recommendation:*** Amend §438.62(b)(1)(i) as follows: *The enrollee has access to services consistent with the access they previously had, **including access to currently authorized treatments without additional assessment, prior authorization, or utilization management requirements**, and is permitted to retain their current provider for ~~a period of time~~ **the duration of their course of treatment or scheduled procedure including any necessary follow-up appointments, or—in the case of a pregnant or post-partum enrollee—until 60 days post-partum, or—in the case of an enrollee with a terminal illness—for the duration of the illness, or—in the case that the state identifies other circumstances that warrant continued access—for a period of time identified by the state**, if that provider is not in the MCO, PIHP or PAHP network.*

## **State monitoring requirements**

We note that the state monitoring requirements proposed at §438.66 are not applied to CHIP. We believe these requirements should be applied to CHIP because, as with Medicaid, strong state management and oversight is critical.

**Recommendation:** Apply §438.66 to CHIP. See our comments related to §438.66 as proposed below.

*We commend HHS for clarifying, consolidating, and expanding state monitoring requirements and requiring states to use data collected to improve the performance of its managed care program. While a number of these requirements are found in the current regulations, such as monitoring grievances and appeals, some states have*

*done a poor job in conducting monitoring activities and using the information collected. Moreover, the lack of federal monitoring of state compliance has resulted in managed care programs that fail to meet the needs of enrollees.*

*The proposed regulation requires states to have a “system” for monitoring key areas. However, as explained below, we urge HHS to impose more specific requirements and guidelines on the state monitoring system. These include transparency and reporting requirements, mandatory reporting of data, performance, and monitoring activities, and robust stakeholder consultation and engagement.*

*State monitoring activities should coordinate with the state and managed care Drug Utilization Review, inform the development of the state quality strategy, and provide a formal role for the Medical Care Advisory Committee and the state and LTSS stakeholder groups. State monitoring should also include audits and performance reviews conducted outside the EQR process, such as investigations and reports issued by state inspectors general, auditors, comptrollers, and other entities. Thus, we urge HHS to recognize the indispensable role of such independent monitoring – not only for managed care plans, but state agencies as well.*

*We strongly support the inclusion of a requirement for data collection pursuant to state monitoring requirements to improve performance of the managed care program. The current monitoring and reporting requirements result in the provision of fragmented program information by states, impeding oversight efforts. However, the proposed regulation contains no transparency requirement for the data collected, and no opportunity for consumers and community stakeholders to evaluate the data. Therefore, we urge HHS to require states to report on their monitoring activities and share data collected with the MCAC and the state LTSS stakeholder groups on, at minimum, a quarterly basis. We also urge HHS to require states to monitor the adequacy of the prescription drug formularies offered to Medicaid managed care enrollees, including use of the exceptions process allowing enrollee access to non-formulary drugs and for off-label uses.*

*The proposed rule requires states to monitor provider network management. (§438.66(b)(10)). We agree that monitoring provider networks is essential for ensuring that enrollees have actual access to providers and services. Therefore, we urge HHS to clarify that monitoring provider network management includes monitoring adherence to network adequacy standards required under §438.68, timely access standards required under §438.206(c)(1) and provider directories under §438.10(h). Moreover, HHS should specify that monitoring must include direct testing for compliance with network adequacy and timely access standards. State monitoring and direct testing should be in addition to EQR validation of network adequacy standards.*

*According to the HHS Office of the Inspector General (OIG), direct testing of provider networks is the most effective means of evaluating adherence with network adequacy standards.<sup>6</sup> As the OIG noted, fluctuating and inadequate provider networks, as well as*

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<sup>6</sup> See HHS Office of the Inspector General (“OIG”), [State Standards for Access to Care in Medicaid Managed Care](#) (Sept. 2014), and OIG, [Access to Care: Provider Availability in Medicaid Managed Care](#) (Dec. 2014).

*inaccurate provider directories, significantly impede timely access to services. By requiring ongoing state monitoring of provider directories, network adequacy and timely access standards in addition to EQR validation, HHS can strengthen oversight and help ensure enrollees can actually access providers and services.*

*In addition, we urge HHS to clarify the requirements governing medical management committees described in proposed §483.66(c)(7). We agree that any committee reports and minutes should be considered as part of performance improvement activities and should be publicly available. However, the duties, membership, and authorities of these committees are unclear and are not defined elsewhere in the regulation. Any medical management committee operated by the state, MCO, PAHP, PHIP, or PCCM entity should be subject to transparency requirements including open meetings and stakeholder participation.*

***Recommendation:*** Amend §438.66(c) as follows: ***The State must report on its monitoring activities under subsection (b) and provide the data collected to the Medical Care Advisory Committee established under §431.12 of this chapter or an advisory committee with similar membership, and the stakeholder consultation group specified in §438.70, at minimum, on a quarterly basis. The State must use data collected from its monitoring activities to improve the performance of its managed care program, including at a minimum:***

***Amend subparagraph (10) as follows: Provider network management, including direct testing of provider directories, network adequacy, and timely access standards required under §§438.10(h), 438.68, and 438.206(c)(1).***

***Add new subparagraphs as follows: (13) Data collected by DUR activities conducted by the state, MCO, PAHP, PHIP, or PCCM entity including, but not limited to overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications.***

***(14) Monitor the adequacy of the MCO, PAHP, PHIP, or PCCM entity (if applicable) prescription drug formulary, including data on enrollee education and utilization of the exceptions process required under §438.3(s)(7) for non-formulary and off-label drug uses.***

#### **§457.1218 Network adequacy standards**

We support the addition of network adequacy standards to CHIP at §457.1218 and their alignment with Medicaid at §438.68. We made some comments with respect to §438.68 that are repeated here for easy reference.

*We support the goal of the proposed rule to establish a framework for regulating and ensuring access to providers in Medicaid managed care. This is particularly important as more than two-thirds of children in Medicaid and CHIP receive their coverage*

through managed care arrangements.<sup>7</sup> We concur with HHS that the adequacy of a managed care plan's network ought to be a primary component of any assessment of a state's managed care program.

In this context, we laud many aspects of the proposed rule's efforts to ensure that enrollees in managed care plans have access to needed services, and we identify these areas of agreement below. However, we also suggest a central tension inherent in the proposed rule that may hinder efforts to regulate network adequacy in managed care plans. On the one hand, the proposed rule seeks to align network adequacy requirements with other coverage programs, particularly Medicare Advantage Plans and QHPs sold through the Marketplace. At the same time, the proposed rule aims to maintain state flexibility. Aligning standards across coverage programs and maintaining state flexibility are both worthy goals, but can potentially work at cross-purposes. In light of these issues, we recommend that CMS maintain a degree of state flexibility while also establishing minimum, multi-faceted, quantitative standards for network adequacy, such as appointment wait times, provider-patient ratios for adult and pediatric primary and specialty care, and time and distance standards for primary care and adult specialty care. We strongly caution against the sole use of time and distance for pediatric specialty care. The lack of access to a pediatric specialty facility resulting from the sole use of a distance standard for network adequacy could delay services for very sick children or compel them to seek care in settings ill-equipped to address their pediatric service needs.

#### *§438.68(a) General rule*

We support the proposed rule's requirement articulated in §438.68(a) that a state that contracts with a managed care organization must develop network adequacy standards. However, we are concerned that the proposed rule's efforts to maintain state flexibility will result an overly fragmented system that will undercut the goal of aligning standards across coverage programs and may not effectively ensure that those enrolled in Medicaid managed care plans have adequate access to care across all states. The proposed rule requires that states set minimum time and distance standards while also proposing additional metrics that states might adopt to ensure access to care. There are a variety of ways in which states might exercise flexibility in regulating their managed care markets.

#### *§438.68(b) Provider-specific network adequacy standards*

Establish national quantitative standards to ensure access. We recommend that HHS go further than requiring states to set time and distance standards for network adequacy and urge the final rule to also create a national floor for state standards in this regard. We propose the following serve as a floor for such standards: that a provider is available within 30 minutes or 15 miles of the residences or workplaces of 90 percent of enrollees for primary care (adult and pediatric), behavioral health (adult and pediatric), pediatric dental providers, hospitals, pediatric tertiary care and pharmacies, and that specialist providers (adult and pediatric) and birth centers are

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<sup>7</sup> S. Burwell, "2014 Annual Report on the Quality of Care for Children in Medicaid and CHIP," United States Department of Health and Human Services (November 2014), available at <http://www.medicaid.gov/medicaid-chip-program-information/by-topics/quality-of-care/downloads/2014-child-sec-rept.pdf>.

available within 60 minutes or 30 miles of the residences or workplaces of 90 percent of enrollees. Establishing such standards would ensure a minimum level of access for beneficiaries while providing states with the ability to implement their own higher standards for time and distance or other metrics as they see fit.

**Recommendation:** Set a national floor for time and distance standards at §438.68(b).

However, we urge that the final rule also require that in setting their own specific standards for time and distance, states take into account whether a majority of enrollees use public transportation in calculating travel times. Doing so will help ensure that these standards are designed with the needs of the population that Medicaid serves in mind. Along these lines, the final rule might also require that states establish quantitative standards regarding provider hours and availability.

**Recommendation:** Take into account that many Medicaid beneficiaries rely on public transportation when calculating travel times. Consider including quantitative standards regarding provider hours and availability.

We also support establishing a floor for standards regarding appointment wait times. Such a standard is especially important for the population that Medicaid serves that may face difficulty in taking time off of work or arranging for child care in order to make it to a medical appointment. Since a long wait time at a provider's office could disrupt such arrangements, we propose that for any routine, preventive, or non-urgent appointments, the in-office waiting time should not exceed 30 minutes from the time of the scheduled appointment.

**Recommendation:** Establish maximum appointment wait time standards.

Given the importance of primary care providers for all enrollees but especially children, we recommend that the final rule also include national standards regarding provider-patient ratios for adult and pediatric primary care, at one adult primary care provider for each 1200 adult enrollees and one pediatric primary care provider for each 1000 enrollees under 21.

**Recommendation:** Establish a national standard for primary care provider to patient ratios.

We also suggest that the final rule more specifically delineate a managed care plan's obligations to ensure that enrollees with specialized needs receive care. Given the regionalized nature of specialty care, especially specialty pediatric care, we urge HHS to include in the final rule a requirement that plans arrange for care to be provided by a geographically-proximate out-of-network provider or provide transportation for an enrollee to travel to an in-network provider that is located beyond the maximum time and distance. HHS should also actively monitor how plans provide out of network care.

**Recommendation:** Require managed care plans to provide out-of-network care or transportation to in-network care outside the maximum time and distance standards for enrollees with specialized needs.

In addition, we urge HHS to require that managed care organizations include in their provider directories information on network tiering of physicians as well as any changes in cost sharing and out of pocket charges that enrollees may encounter when using out of network providers. See comments on §438.10(h).

**Recommendation:** Monitor provision of out-of-network care and ensure up-to-date information is provided to enrollees in their provider directories.

*Consider unique needs of specific populations.* We also support the proposed rule's stipulation at §438.68(b) of specific network provider types for which such standards must be established, including both adult and pediatric primary care, OB/GYN, behavioral health, adult and pediatric specialist care, hospitals, pharmacies, and pediatric dental. The health care needs of children and adolescents differ from those of adults in many respects, and therefore we strongly support the inclusion of pediatric-specific standards and recommend that HHS consider the full range of required types of pediatric providers for whom network adequacy standards should be developed so children's full scope of health care needs are appropriately addressed.

In this regard, we concur with HHS that states specifically include pediatric primary, specialty, and dental providers but also urge HHS to include a requirement that states establish standards for pediatric behavioral health providers. With regard to behavioral health specifically, we urge HHS to prohibit any behavioral health carve-outs in the final rule, and that any requirement regarding access also apply equally to behavioral health. If behavioral health carve-outs cannot be prohibited, we urge HHS to require direct access to specialty care providers as needed.

**Recommendation:** Consider the full range of pediatric providers for whom particular network adequacy standards should be developed. Establish time and distance standards for pediatric behavioral health providers. Prohibit behavioral health carve-outs, or alternatively, require plans to allow direct access to specialty care providers as needed.

With respect to the importance of recognize the distinction between pediatric and adult care, we urge the final rule to require managed care organizations to document how children with chronic conditions move from pediatric to adult providers as they "age out" of pediatric care.

**Recommendation:** Monitor the transition from pediatric to adult providers as children with chronic conditions "age out" of pediatrics.

#### *§438.68(c) Development of network adequacy standards*

We also strongly endorse the proposed rule's inclusion of a requirement that states consider the availability of network providers to communicate with LEP enrollees in their preferred language when the state is developing time and distance access standards.

**Recommendation:** Maintain the requirement sat §438.68(c)(1)(vii) and (viii) to consider access for LEP enrollees and individuals with disabilities.

#### *§438.68(e) Publication of network adequacy standards*

*Promote monitoring and transparency.* In addition to establishing important requirements to ensure access, the proposed rule's provisions regarding network adequacy would also enhance transparency, both in general and with regard to specific categories of enrollees. We support the proposed requirement from §438.68(e) that states publish their network adequacy standards, though we encourage the final rule to go further and require that these state-level standards in turn be published via a federal platform such as Healthcare.gov or Medicaid.gov, given that these sites serve as points of access and sources of information for many Medicaid enrollees. We also support requiring states to publish their network adequacy standards and make these standards available, at no cost to individuals with disabilities in alternate formats. Along these lines, we appreciate that §438.207 requires states to provide

*documentation underlying their certification of Medicaid plan networks to HHS, and request that the final rule also require states to make the information that they collect during the monitoring process available to the public. Similarly, we urge that any efforts that states may take to monitor network adequacy (for example, enrollee or provider surveys, audits of appointment requests and encounter data, and ‘secret shopper’ studies) are also made available to the public.*

***Recommendation:*** *Require states to publish network adequacy standards on a federal platform. Make the documentation underlying Medicaid plan network certification and state monitoring efforts public.*

*More generally, we encourage HHS to include in the final rule mechanisms to monitor the impact of the network adequacy requirements on specific populations, especially children. This will help states to make adjustments to their standards as needed should specific metrics not ensure enrollee access to providers as intended. We also urge HHS to monitor any material changes to the composition of a plan’s provider network, such as a change in the size or demographic characteristics of the enrolled population or the termination of a provider contract. We believe that requiring states to actively monitor and publically release information on how plans are complying with network adequacy requirements and how these rules affect enrolled populations will produce information that can be utilized by enrollees, regulators, and other stakeholders to improve access to care for children and families in Medicaid. This monitoring requirement can also serve as a useful enforcement tool.*

***Recommendation:*** *Monitor the impact of network adequacy requirements on specific populations, especially children. Monitor material changes to the composition of a plan’s provider network. Make the data underlying such monitoring and the results of such monitoring publicly available.*

We note that §438.68(b)(iv) and §438.68(b)(vii) require time and distance standards for pediatric specialists and pediatric dental, respectively, so we believe that the second sentence at §457.1218 is not necessary.

As noted above, we also recommend that CHIP expressly adopt the state monitoring requirements provisions at §438.66. We note that the report referenced at §438.66(e)(1) is applicable to CHIP through adoption of §438.68, but we believe that the state monitoring system should be applicable across the board.

***Recommendation:*** Amend §457.1218 by deleting the second sentence with respect to additional requirements for pediatric specialists and dentists, as that requirement is already captured in §438.68. Add state monitoring requirements for CHIP by adopting §438.66.

### **Beneficiary support system**

We noted that the proposed rule does not include a provision requiring a beneficiary support system in CHIP like the one in Medicaid at §438.71. While we recognize that choice counseling is not always relevant to CHIP because there may only be one option at

enrollment, we believe that other aspects of the beneficiary support system are applicable and therefore recommend adding a new section to subpart L of part 457. The health insurance market is complex, and CHIP beneficiaries would benefit from assistance navigating it. Such a section could be modeled on the Medicaid requirement at §438.71, with a few modifications. For example, the provisions specific to choice counseling should only apply to CHIP when there is more than one option to choose from. Even when choice counseling is inapplicable, CHIP beneficiaries would benefit from assistance understanding managed care, outreach activities promoting enrollment, and assistance with the grievance and appeals processes. When possible, the CHIP beneficiary support components could be integrated in the larger, Medicaid beneficiary support system. When such integration is not possible, the burden of developing a beneficiary support system just for CHIP increases, but we believe consumers need this additional assistance.

**Recommendation:** Add a new section to subpart L requiring a beneficiary support system that is tailored to meet the needs of CHIP beneficiaries.

Our comments related to the Medicaid BSS are repeated here for easy reference.

*§438.71(a) General Requirement*

*Medicaid managed care has proven to be a difficult system to navigate for consumers, and enrollees often encounter problems related to enrollment and disenrollment, service denials, enrollee rights, and provider network limitations. We often hear beneficiaries report frustrations in accessing services, understanding their rights and how to enforce them, and the lack of assistance when they encounter problems. Therefore, we strongly support the creation of a mandatory beneficiary support system (BSS) to help beneficiaries choose the most appropriate managed care entity to meet their needs; provide assistance and education in understanding managed care, including enrollee rights and mechanisms for advocacy; and provide assistance in navigating the grievance and appeal process. Knowledgeable professionals must perform these activities in a conflict-free manner that is accessible and meaningful for that individual and/or the individual's caregivers. As much as we support having a BSS, we are concerned that as written, the BSS will not provide the services needed by all enrollees. We therefore urge that the BSS requirements be revised to ensure that it will truly meet the needs of enrollees in Medicaid managed care, especially as it continues to evolve and become more complex.*

*At §438.71(a), we suggest adding a reference to caregivers and to move the requirement from §438.71(e)(3)(i) with respect to representation in order to ensure equal access to representation regardless of whether the beneficiary is using LTSS.*

**Recommendation:** *Revise §438.71(a) to add a reference to caregivers; eliminate the distinction between the services for beneficiaries and those in or seeking LTSS with respect to representation:*

*(b) General requirement. The State must develop and implement a beneficiary support system that provides support to beneficiaries **and/or caregivers** both prior to and after enrollment in a MCO, PIHP, PAHP, PCCM or PCCM entity.*



**(1) An entity that receives non-Medicaid funding to represent beneficiaries at hearings, may, subject to approval by HHS, establish firewalls to provide choice counseling as an independent function.**

**(2) [Reserved]**

§438.71(b) Elements of the support system

A core function of the BSS is to conduct outreach, which is important but insufficient. Enrollees and potential enrollees should have access to education and training on par with those received by managed care entities or providers. Accordingly, we recommend clarifying that all current and potential beneficiaries be included in §438.71(b)(1)(iii). Although training is listed as a minimum function of the proposed system, this training is only for MCOs, PHIPs, PAHPs, PCCMs, PCCM entities, and network providers. While we understand the proposed training is intended for the benefit of beneficiaries, it does not directly support them. In our experience, there is dearth of training for beneficiaries such that very few understand their rights or how to self-advocate in managed care. As described below, we believe that the proposed requirements in §438.71(e) should not be limited to beneficiaries who use LTSS; therefore we have incorporated those requirements into subsection (b).

**Recommendation:** Amend §438.71(b) as follows: Elements of the support system.

(2) A State beneficiary support system must, ~~include~~ at a minimum:

(i) **Provide** ~~choice counseling for all beneficiaries;~~

(ii) **Provide** training for network providers as specified in paragraph (d) of this section;

(iii) ~~Assistance for~~ **all enrollees and potential enrollees** in understanding managed care;

(iv) **Perform outreach to beneficiaries and/or caregivers;**

(v) **Provide education on enrollees' grievance and appeal rights within the MCO, PIHP or PAHP; the State fair hearing process; enrollee rights and responsibilities; and additional resources outside of the MCO, PIHP or PAHP;**

(ix) **Assist, upon request, in navigating the grievance and appeal process within the MCO, PIHP or PAHP, as well as appealing adverse benefit determinations by the MCO, PIHP, or PAHP to a State fair hearing. The system may not provide representation to the enrollee at a State fair hearing but may refer enrollees to sources of legal representation; and**

(viii) **Be accessible in multiple ways including phone, internet, in-person, and via auxiliary aides and services when requested.**

(2) The beneficiary support system must: **provide review and oversight of system program data to provide guidance to the State Medicaid Agency on identification, remediation and resolution of systemic issues.**

~~(i) perform outreach to beneficiaries and/or authorized representatives and~~

~~(ii) be accessible in multiple ways including phone, Internet, in-person, and via auxiliary aids and services when requested.~~

§438.71(e) Functions specific to LTSS activities

*We further recommend that the BSS include education for all enrollees in navigating the grievance and appeals process, not just LTSS beneficiaries. Specifically, the education and navigation assistance functions set forth in paragraphs (e)(2) and (e)(3) should not be limited to LTSS beneficiaries, but be included as minimum functions of the BSS generally. While we agree that it may be more likely that LTSS beneficiaries need additional assistance, there are non-LTSS beneficiaries who have similar needs in navigating the managed care system. For instance, there are many people with disabilities who do not receive LTSS but likely encounter similar or more severe difficulties in accessing care through managed care. In addition, other populations, such as those seeking services that are carved-out or women encountering refusals for reproductive health services who may need to go out of network, may need assistance in understanding their rights and responsibilities as well possibly navigating the grievances and appeals process. Therefore, this would have an added benefit of ensuring that the state would be better informed about how managed care is functioning for beneficiaries if the provisions of (e)(4) regarding identification of systemic issues to the state was for managed care generally, and not just LTSS. We recommend clarifying §438.71(e)(1) to more fully explain how this proposed access point for complaints and concerns would function and what the relationship would be to the grievance and appeals process of subpart F. It is not clear whether the BSS would direct the person to the managed care entity's grievance and appeal process or whether HHS is proposing a separate complaint process that would be managed by the BSS. In either case, we are concerned about the high likelihood of confusion for beneficiaries regarding how they should complain about issues regarding their managed care entity and what their expectation should be about complaining through different processes.*

*We believe there are specific purposes in filing a grievance with the managed care plan through the process set forth in subpart F, including providing a chance to resolve the issue and ensuring that the grievance is recorded and part of the records reviewed by the state as part of its ongoing monitoring. Plans already have an incentive to address beneficiary complaints such that they do not become official grievances in order to convey the impression to the state that enrollees are satisfied with the plan even when they are not. If there is an alternate mechanism for complaint, plans could have an even greater incentive to redirect complaining beneficiaries to the BSS system if it is not effective.*

*We propose that the role of the BSS regarding resolving beneficiary issues with plans be to educate the beneficiary about their rights related to the issue, inform them how to file a grievance or appeal with the managed care entity, provide assistance where necessary, and track the subject of the complaint and the entity involved for reporting to the state about trends and systemic issues. We further believe that when a grievance is not resolved to the satisfaction of the beneficiary that fact should be reportable to the BSS by the beneficiary. Reporting such a complaint to the BSS would give the BSS and the state information about enrollee satisfaction and the function of a managed care entity's grievance system, and would give the beneficiary an opportunity to take the subject of the grievance outside of the closed system of the managed care entity. The BSS's role in grievances would not be to resolve them for the beneficiary, but to include them in the report on systemic problems. However, as part of navigating this*

*part of the system, the BSS could provide information to the beneficiary about the relevant rights involved in the grievance to help the beneficiary better understand the response.*

*We also agree that an entity that receives non-Medicaid funding to represent beneficiaries at hearings, should, subject to approval by HHS, be able to provide choice counseling as an independent function (§438.71(e)(3)(i)). We firmly support extending the ability of non-Medicaid funded entities that represent beneficiaries at hearings, including protection and advocacy organizations and others that are federally-funded, to be allowed to contract with the Medicaid agency to provide choice counseling with appropriate firewalls. In our experience, protection and advocacy organizations are well versed in providing accessible information and education about managed care options and processes. The same is true of legal services organizations with experience in representing Medicaid beneficiaries. We also suggest that states be allowed to contract with such entities for all BSS functions as many already do similar work.*

**Recommendation:** *Strike §438.71(e) and instead incorporate these provisions, with greater specificity regarding the role of the BSS in the grievance and appeals processes, as shown in the recommendation for §438.71(b), above.*

#### *§438.71(c) Choice Counseling*

*We appreciate that the BSS would have to meet the independence and freedom from conflict of interest standards if an individual or entity provides choice counseling on the state's behalf (§438.71(c)(2)). A BSS should be as independent from the state as possible to ensure effective support and advocacy for beneficiaries and a lack of conflict of interest in relation to the managed care entities. Entities that already have adversarial relationships, even if only from appeals, clearly do not have an interest in the managed care entity or the state's relationship with such an entity. If this proposed system is supposed to truly help beneficiaries and support them in understanding and effectively navigating the system, the BSS should be sufficiently apart from the state or the managed care entities. As shown with the history of the protection and advocacy systems in which many have moved from state-based divisions to independent entities, there is value in having an entity that supports beneficiaries be separate from the state. Based on the experience of some states that have similar programs, there is also value in separating choice counseling, which may be more associated with the state, and the other functions of a BSS.*

*We note that states should be encouraged to contract with existing entities that provide consumer assistance in enrolling in health plans, including navigator and SHIP entities. We also believe that federally-qualified health centers (FQHCs) serve an important function as enrollment counselors operating with funding from the Health Research and Services Agency and are bound to serve the best interests of consumers as detailed in 42 CFR 155.225. We encourage HHS to consider options that would allow FQHCs to serve as choice counselors. Finally, we believe that the BSS may also serve a useful role in helping beneficiaries renew their Medicaid enrollment, and HHS should consider adding renewal assistance as a BSS function.*

## C. Enrollee Rights and Protections

### §457.1224 Marketing activities

We support aligning the marketing activities with Medicaid at §457.1224 by cross reference to §438.104. As noted in our comments on §438.104, we do not believe that QHPs should be excluded from the definition of private insurance because we are concerned that such an exclusion would allow QHPs with Medicaid and CHIP enrollment information to target current enrollees without abiding by any of the marketing safeguards. Our comments related to §438.104 are repeated here for easy reference.

*We strongly support the continuance of restrictions on marketing activities in that the NPRM carries forward all of the prior provisions in §438.104.*

*We support the inclusion of PCCM entity as a type of entity to which the marketing provisions apply but note that it was inadvertently excluded in the definition of 'Marketing materials' under §438.104(a)(2).*

*We support the inclusion of text messages and emails as types of activities that are considered cold-call marketing at §438.104(b)(1)(v).*

*After some consideration, we find it difficult to support HHS' decision to exclude QHPs in the definition of 'private insurance' at §438.104(a)(2). We understand that this provision is intended to level the playing field for QHPs and non-QHPs, since HHS and states have no authority over the conduct of non-QHPs. However, excluding QHPs from the marketing provisions means that they do not have to abide by any of the safeguards afforded beneficiaries in this provision and yet have enrollment information that allows them to target current enrollees. We recommend deleting this exclusion. Additionally, we recommend codifying guidance provided in a January 16, 2015 Frequently Asked Questions, regarding the role managed care plans may play to assist in state efforts to renew beneficiaries.*

***Recommendation:*** Amend §438.104(a) by striking the last sentence of the marketing definition and adding a new sentence regarding educational materials. Marketing means any communication, from an MCO, PIHP, PAHP, PCCM or PCCM entity to a Medicaid beneficiary who is not enrolled in that entity, that can reasonably be interpreted as intended to influence the beneficiary to enroll in that particular MCO's, PIHP's, PAHP's, PCCM's or PCCM entity's Medicaid product, or either to not enroll in, or to disenroll from, another MCO's, PIHP's, PAHP's, PCCM's or PCCM entity's Medicaid product.

***Materials and information that purely educate an enrollee of that Medicaid managed care plan on the importance of completing the State's Medicaid eligibility renewal process in a timely fashion does not meet the federal definition of marketing if the information and outreach about the eligibility renewal process is neither directed to beneficiaries who are not enrolled with that Medicaid managed care plan, nor intended to influence the beneficiary to enroll in that particular Medicaid managed care plan—or to not enroll in, or disenroll from another Medicaid managed care plan.***

*Marketing does not include communication to a Medicaid beneficiary from the issuer of a qualified health plan, as defined in 45 CFR 155.20, about the qualified health plan.*

**Recommendation:** Amend §438.104(a) by striking the definition of private insurance. *Private insurance does not include a qualified health plan, as defined in 45 CFR 155.20.*

*If HHS chooses to maintain the exclusion for QHPs, we recommend that it establish some guardrails to assure that beneficiaries are protected and that QHPs meet the spirit of the current regulations in some way, such as the NHeLP's recommended changes to §438.104(c).*

## **Additional enrollee rights and protections**

We would like to highlight two provisions in the enrollee rights and protections section of the Medicaid rules that were not adopted in CHIP and suggest that HHS consider adding them. First, §438.108 requires the managed care contracts comply with Medicaid's cost sharing rules at §447.50-82. We believe that the CHIP cost sharing rules should be similarly applied to the CHIP managed care contracts and recommend that a new section be added to subpart L of part 457 to include a reference to the CHIP cost sharing rules at §457.505-560. Second, §438.116 requires compliance with certain solvency standards. We note that the definition of managed care organization at §457.10 includes a reference to the solvency standards at §438.116, but we believe that a provision should be added to subpart L of part 457 to reflect the solvency rules.

**Recommendation:** Add a provision to subpart L of part 457 to require compliance with CHIP cost sharing rules. Add a provision to subpart L of part 457 to require compliance with the solvency standards in §438.116.

## **D. MCO, PIHP and PAHP Standards**

### **§457.1230 Access standards**

We support application of the availability of service standards from §438.206 to CHIP at §457.1230(a). We recommended some changes to §438.206 that we repeat here for easy reference, as we believe these changes should be reflected in CHIP as well.

*We appreciate that HHS will continue to require plans to ensure that their provider networks are adequate, as supported by written agreements. We especially commend HHS' addition of language to this section aimed at ensuring that Medicaid plans contract with providers who are accessible to LEP enrollees and enrollees with disabilities. We suggest a small change to the text to clarify these provisions. In addition, we recommend that HHS provide additional language to clarify what is meant by the term "services" in this section. This language should clarify that all service providers—including those who provide services like durable medical*

equipment and orthotic devices—must be considered when the plan reviews the sufficiency of its network.

**Recommendation:** *We recommend amending §438.206(b)(1) as follows: Maintains and monitors a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to all services covered under the contract, **to the extent those services are covered by the State plan and the MCO, PIHP, or PAHP contract, in accordance with the requirements of §438.68(c) of this chapter, including access by those with limited English proficiency or physical or mental disabilities.***

We support the application of the assurances of adequate capacity and services from §438.207 to CHIP at §457.1230(b). We do not have any CHIP-specific comments to this subsection, but repeat our related Medicaid comments here for easy reference.

*We appreciate that HHS is proposing to continue requiring plans to document their compliance with access to care requirements in §438.207. In conjunction with §438.206 and the new proposed §438.68, this section will go a long way toward ensuring that that Medicaid managed care enrollees can access covered services. Recent evidence suggests that even when states adopt generous consumer protections in Medicaid managed care aimed at ensuring access to services, access can fall short when compliance with those standards is not adequately monitored or enforced.<sup>8</sup> Thus we strongly recommend that HHS add language to this section to spell out in more detail how states should monitor plans to make sure that they are providing adequate access to care, and what kinds of monitoring tools and reporting states must employ, as described in the NHeLP's specific comments to §438.207.*

We also support the application of the coordination and continuity of care standards from §438.208 to CHIP at §457.1230(c). While the CHIP population may not have as many chronic or LTSS needs as the Medicaid population, children with chronic conditions and other special health care needs would benefit from inclusion of these coordination standards and therefore they should be preserved. We do not have any CHIP-specific comments to this subsection, but repeat our related Medicaid comments here for easy reference.

*We commend HHS for updating this section to more specifically account for the needs of Medicaid plan enrollees with special health care needs and who use LTSS. The additions to this section make significant strides toward ensuring that all Medicaid plan enrollees receive coordinated, appropriate care. We support the NHeLP's specific comments on §438.208 to: narrow the exceptions at §438.208(a), strengthen the care coordination requirements at §438.208(b) and protect against conflicts of interest at §438.208(c).*

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<sup>8</sup> See, e.g., ELAINE M. HOWELL, CAL. STATE AUDITOR, IMPROVED MONITORING OF MEDI-CAL MANAGED CARE HEALTH PLANS IS NECESSARY TO BETTER ENSURE ACCESS TO CARE (2015), available at <https://www.auditor.ca.gov/pdfs/reports/2014-134.pdf>.

In the preamble, HHS notes that rather than complying with the timeliness standards in §438.210(d), CHIP managed care organizations must comply with §457.1160. Yet it seems inconsistent with the alignment principle to allow a standard timeline in CHIP of 90 days when Medicaid coverage decisions must be made within 14 days. Both Medicaid and CHIP include an expedited timeframe of 72 hours as needed. We recommend that both the standard and expedited timeframes be aligned and as short as is reasonable.

**Recommendation:** Preserve the coordination and continuity of care standards. Align the CHIP and Medicaid timeframes to be as short as is reasonable, such as 14 days for standard decisions and 72 hours for expedited decisions.

#### **§457.1233 Structure and operation standards**

We support full alignment with the quality assurance standards, including the structure and operation of managed care contracts and the measurement and improvement standards. We note that the confidentiality provisions set forth in §438.224 are not adopted, in favor of existing rules at §457.1110. We support reliance on the existing CHIP standards, but as noted above related to §457.1206 Non-emergency medical transportation PAHPs, we believe the standards at §457.1110 should be expressly applied to subpart L of part 457.

**Recommendation:** Apply the standards at §457.1110 related to confidentiality to subpart L of part 457.

### **E. CHIP Quality**

#### **§457.760 CHIP component of the state comprehensive quality strategy**

We support the provision at §457.760 to incorporate CHIP into a single, state comprehensive quality strategy that includes all children in Medicaid and CHIP in order to promote efficiency and alignment. We strongly encourage HHS to work with states to ensure that the needs of children and pregnant women in Medicaid and CHIP are taken into consideration as the state comprehensive quality strategies are developed. Our comments related to §§431.502 and 504 are repeated here for easy reference.

##### *§431.502 State comprehensive quality strategy*

*We applaud HHS for requiring states to conduct a comprehensive quality strategy across all aspects of Medicaid and CHIP. We believe this effort can bring a renewed focus on the quality of care provided to Medicaid beneficiaries and presents an opportunity for HHS to focus on healthy child development and the needs of children with special health care needs. We urge HHS to require states to specifically consider pediatric quality improvement in any comprehensive strategy and use a range of pediatric measures that capture the needs of all subpopulations of children, including children with complex medical needs.*

*We support HHS' proposal to extend the requirements of the state comprehensive quality strategy (CQS) beyond managed care to incorporate additional types of managed care and Medicaid fee-for-service (FFS) delivery as well. While enrollment in managed care has grown considerably in recent years, more than a quarter of Medicaid enrollees still receive services through FFS, and they are often the most vulnerable groups with significant health care needs. This change will help improve monitoring and oversight of the FFS system by requiring states to set measurable goals and objectives for quality improvement and select specific measures to be collected and published at least annually on the state's website.*

*In §431.502(b)(1), HHS proposes that each state's CQS must establish goals and objectives to "take into consideration the health status of all populations served by the Medicaid program." We suggest that HHS add language to ensure that "health status" is understood broadly to include mental health, functional status and quality of life as well. We also noted an absence of specificity in the proposed rules that recognizes that the quality measurement and performance improvement strategies differ for children and adults, and differ for healthy children compared to children with special health care needs. Similar distinctions apply to pregnant women compared to the general adult population. We believe it is vitally important that HHS bifurcate its approach to quality activities to account for these differences.*

*We also urge HHS to require states to include in their CQS a plan to assess, address and reduce health disparities in the state. The ACA requires "any federally conducted or supported health care or public health programs, activities or surveys" to collect and report data stratified by race, ethnicity, sex, primary language, geography and disability status to the extent practicable. HHS has moved to implement this mandate for national Medicaid population health surveys and to incorporate it into Medicaid claims database upgrades. But quality measurement in Medicaid managed care has until recently barely addressed the issue of health disparities. Most performance data is reported in aggregate for each health plan and is not broken down by key demographic factors, including age. Stratifying quality data by the key factors called for in the ACA, as well as age, would sharpen quality improvement interventions, identify groups that continue to be left behind, and provide a status report on whether managed care is helping resolve the longstanding inequities in our health care system. We appreciate that HHS has active programs, such as the Child Core Set and CHIPRA Quality Demonstration projects, to help states build capacity to collect data specific to children and implement quality improvement projects. We believe the CQS present an opportunity to spread the use of the pediatric Medicaid/CHIP Core set and continue to leverage and build on the pediatric quality improvement efforts through the Pediatric Quality Measures Program (PQMP). In addition to placing a stronger emphasis on pediatric quality, we encourage HHS to:*

- Replace less impactful measures with validated measures coming out of the PQMP and other sources relevant to the various populations served by Medicaid;*
- Ensure a pipeline of much needed pediatric quality of care and outcomes (health and cost) measures. Clinical evidence, science, and data availability*



*changes over time, and we want pediatric measures to be responsive to these changes so they accurately reflect the quality of care for children; and*

- *Require the reporting of a minimum core set to move away from voluntary reporting in order to better demonstrate trends and understand how the Medicaid program operates across the country.*

*We would be remiss to ignore the fact that this NPRM mentions the word disparities only once, and only in the context of network adequacy, not quality measurement. And yet addressing health disparities should be a top priority in quality measurement and improvement. HHS has also produced reports with recommendations on how to improve data collection for health disparities in Medicaid and CHIP. We urge HHS to take advantage of this opportunity to advance the requirements of the ACA and ensure that states develop quality measurement programs with the capacity to evaluate health disparities and make the necessary steps to eliminate them a priority.*

*We cannot overemphasize that disparities and health care needs vary by age group. Children and the elderly have unique needs, as do individuals with special health care needs. Notably, since children are generally healthy, and therefore, less costly to cover, their needs are not always the focus of quality initiatives in managed care. And yet the more we do to assure the health of children before they reach adulthood, the greater likelihood that we can reduce long term health care costs. To that end, we believe that stratification of data should always include age and health status.*

***Recommendation:*** Amend §431.502(b)(1) to include a broad understanding of health that includes an individual's quality of life and well-being: (1) The State's goals and objectives for continuous quality improvement, which must be measurable and take into consideration the health status **and quality of life** of all populations served by the Medicaid program.

***Recommendation:*** Add a new paragraph (b)(3) to include an element that requires states to develop a plan to assess, address, and reduce health disparities. **(3) The state's plan to identify, evaluate and reduce health disparities through its quality improvement strategy, including efforts to expand the collection and reporting of performance data stratified by age, race, ethnicity, sex, primary language, geography and disability status and actions taken to reduce health care disparities.**

*§431.504 State comprehensive quality strategy development, evaluation, and revision*

*We support HHS' proposal to require states to solicit stakeholder feedback and conduct a public comment process during the drafting and revision of the state CQS. We also agree with the requirement that states consult with the Medical Care Advisory Committee (MCAC), which will help clarify and expand the role of these required stakeholder advisory groups.*

*However, we strongly urge HHS to strengthen and add specificity to this requirement for public input. Without clear requirements to solicit, consider and respond to public comment, meaningful stakeholder engagement is difficult to secure. In other Medicaid contexts that require formal comment, some states have buried hearing and comment notices in obscure locations on their website, produced draft plans so lacking in detail that no meaningful comment is possible, or submitted to HHS "revised" drafts that do not include a single change to the original proposal. To avoid such problems and*

*ensure meaningful stakeholder engagement in the proposed CQS drafting process, we urge HHS to add significant detail to flesh out its vision for a robust CQS public comment process.*

*We believe the best recent model for transparent public engagement would be the regulations governing the comment process for §1115 demonstration projects. This approach includes a 30-day comment period at the state level, a requirement for at least two public hearings and the posting of a detailed draft plan on the state website, and a requirement that the state include a response to public comments collected (along with a description of whether it incorporated these changes) in the draft it submits to HHS. In addition, stakeholders have another 30-day comment period at the federal level for the revised draft. HHS posts all these documents in a single place on its website, which makes it easier to track when new §1115 proposals are up for federal review.*

*If HHS chooses not to include a federal level comment period for CQS, it should at least require in the regulation that states:*

- Provide adequate notice of a public comment period including prominent display on the state website;*
- Conduct well-publicized public hearings to educate stakeholders on the details of the proposed CQS and give them the opportunity to provide direct feedback;*
- Post a detailed and comprehensive draft CQS for comment for at least 30 days;*
- Accept public comments in multiple manners, including electronically, by phone and through the mail; and*
- Submit to HHS (along with its final CQS) a detailed response to stakeholder comments collected, including reasons for altering or not altering the draft in response to those comments.*

***Recommendation:*** Amend 431.504(a) as follows:

***(a)(1) Obtain the input of the Medical Care Advisory Committee, required by §431.12, beneficiaries, and other stakeholders (including Tribal consultation and consultation with the state LTSS stakeholder advisory committee required by §438.70, as appropriate) in the development of the comprehensive quality strategy (and any revisions) and***

***(2) Make the strategy available for meaningful public comment before submitting the strategy to HHS for review. As part of such public comment process, the State must:***

***(i) Post a comprehensive draft of the comprehensive quality strategy that contains a sufficient level of detail to ensure meaningful input from the public on the state's public Medicaid website prior to and throughout the public comment process;***

***(ii) Provide at least a 30-day notice and comment period, and the public notice shall include all of the following information:***

***(A) A summary describing the purpose and content of the comprehensive quality strategy and the public comment process;***

***(B) The locations and Internet address where copies of the draft quality strategy are available for public review and comment;***

***(C) Postal, Internet and email addresses where written comments may be sent and reviewed by the public, and the minimum 30-day time period in which comments will be accepted; and***

***(D) The location, date and time of at least two public hearings convened by the State to seek public input on the demonstration application.***

***(iii) Publish its public notice process, public input process, planned hearings, and the draft quality strategy in a prominent location on either the main page of the public website of the State Medicaid agency or on a quality strategy-specific webpage that is linked in a readily identifiable way to the main page of the State agency's website. The State must maintain and keep current the public website throughout the entire public comment and review process;***

***(iv) Publish an abbreviated public notice which must include a summary description of the quality strategy, the location and times of the two or more public hearings, and an active link to the full public notice document on the State's website in the State's administrative record in accordance with the State's***

***Administrative Procedure Act, provided that such notice is provided at least 30 days prior to the submission of the comprehensive quality strategy to HHS, and in the newspapers of widest circulation in each city with a population of 100,000, or more, provided that such notice is provided at least 30 days prior to the submission of the demonstration application to HHS;***

***(v) Utilize additional mechanisms, such as an electronic mailing list, to notify interested parties of the comprehensive quality strategy;***

***(vi) At least 20 days prior to submitting the quality strategy to HHS for review, the State must have conducted at least two public hearings, on separate dates and at separate locations, regarding the State's quality strategy at which members of the public throughout the State have an opportunity to provide comments. The State must use telephonic and/or web conference capabilities for at least one of the two required public hearings to ensure statewide accessibility to the public hearing.***

***(vii) Provide in its submission to HHS a response to comments collected and to input received from the MCAC, the LTSS stakeholder group, tribes and other stakeholders. The states response must include revisions made (or not made) related to those comments and must be posted on the public website of the State Medicaid agency.***

## §457.1240 Quality measurement and improvement

We support aligning the CHIP and Medicaid quality measurement and improvement rules at §457.1240. We note that in the preamble, HHS references alignment with the full scope of §438.310, but that reference is not expressly included in the regulatory text. We suggest it be added at §457.1240(a).

**Recommendation:** Add a reference to §438.310 at §457.1240(a).

We also made some comments to the Medicaid quality measurement and improvement sections, which we repeat here for easy reference.

### *§438.310 Basis, scope and applicability*

*We support HHS' expansion of the scope of quality measurement requirements to include PAHPs and, for certain provisions, PCCM entities. We agree that as PAHPs have expanded to encompass a broader array of services, they should be subject to the quality standards required of other managed care programs.*

### *§438.320 Definitions*

*We believe the term "access" should include a cross-reference to §438.208, because adequate care coordination and protections moving between providers are important components of access to care, particularly for individuals who require LTSS. The care coordination provision at §438.208 includes standards for direct access to specialists and requires the MCO to have adequate and appropriate staffing to properly manage care, identify individuals with chronic conditions or LTSS needs, and conduct needs assessments and treatment and service plans for such individuals. These facets of care planning are central to the concept of "access" and should be considered as part of the validation of MCO, PIHP and PAHP networks.*

**Recommendation:** Amend the definition of access in §438.320 as follows:

*Access, as it pertains to external quality review, means the timely use of services to achieve the best outcomes possible, as evidenced by successfully demonstrating and reporting on outcome information for the availability and timeliness elements defined under §438.68 (Network adequacy standards), ~~and~~ §438.206 (Availability of services) **and §438.208 (Care coordination).***

*Similarly, the definition of "external quality review" refers to "health care services." We suggest deleting "health care." Alternatively, we suggest defining the term "health care services" to broadly include all Medicaid services covered under the contract, including LTSS.*

**Recommendation:** Amend the definition of "External quality review" in §438.320 as follows: *External quality review means the analysis and evaluation by an EQRO, of aggregated information on quality, timeliness, and access to **all the health care** services that an MCO, PIHP, or PAHP, or their contractors furnish to Medicaid beneficiaries.*

**Recommendation:** Amend the definition of "quality" in §438.320 as follows:

*Quality, as it pertains to external quality review, means the degree to which an*

MCO, PIHP, or PAHP increases the likelihood of desired health-outcomes of its enrollees through...

**Recommendation:** Add a definition for “outcomes” in §438.320: **Outcomes, as they pertain to external quality review, are changes in patient health, functional status, quality of life, goal achievement, or ability to live and engage in community life that result from health care or supportive services.**

Finally, the use of the term “review” in the definition of “validation” could be construed to preclude the creation of new data as part of the validation process, such as through a secret shopper or beneficiary survey used to validate a plan’s network adequacy. We suggest adding a reference to “direct testing of” after “review” to ensure that validation encompasses the types of direct testing HHS proposes will comprise the network adequacy validation protocol laid out in §438.358(b)(4). We also suggest that HHS define the term “direct testing” in the regulations for better clarity. If this change is not made, we recommend requiring direct testing in the EQR protocols that are issued as subregulatory guidance.

**Recommendation:** Amend the definition of validation in §438.320 as follows: Validation means the review **and, when applicable, direct testing,** of information, data, and procedures, to determine the extent to which they are accurate, reliable, free from bias, and in accord with standards for data collection and analysis.

**Recommendation:** Add a definition of “direct testing” in §438.320 as follows: **Direct testing, as it pertains to external quality review, means the proactive testing of managed care plans’ compliance with state standards and requirements, including the accuracy of information maintained and reported by managed care plans. Examples of direct testing include making direct calls to network providers to determine availability and accessibility, conducting systematic evaluations of consumer service calls, and comparing encounter data against a statistically valid sample of individual medical records.**

§438.330 Quality assessment and performance improvement program

On the whole, we support the changes to this section: applying the requirements to PAHPs and establishing a process with active stakeholder input to develop required, standardized measures and select national topics for Performance Improvement Projects (PIPs). This is consistent with HHS’ ongoing work to develop and implement the adult and children core measure sets. States have had several years to voluntarily consider and expand the use of those sets. Having a standard core set of measures for other key populations can enable comparison across states through mechanisms such as the proposed quality rating system and, when coupled with federally selected PIP topics, helps HHS establish and monitor national priorities for health care improvement. National PIPs could help innovation and sharing of best practices for improvement in such priority areas. States will retain flexibility to add other measures to their required set.

We also strongly recommend that HHS provide additional requirements to flesh out the stakeholder engagement and public comment process for selecting national measures and PIP topics. We suggest that HHS, at the very least, lay out in the

*regulations steps for soliciting public comment that include an outreach and education component, a minimum comment period and requirements to include responses to public comments in subsequent drafts. Establishing a quality task force that includes balanced and meaningful representation from various advocates, Medicaid beneficiaries, and their families would help increase awareness and expertise for future revisions of and additions to the core measure set. This could also be achieved through regular required consultations with the state MCACs and, as applicable, LTSS stakeholder advisory groups.*

*While we understand that a particular measure may not be relevant for a certain population, we strongly recommend that HHS strictly limit its proposed exceptions process by enumerating a set of specific reasons when a state may obtain an exception and setting time limits on how long an exemption could last without review and consideration for an extension. HHS requested comment on the possible exceptions process. We agree with HHS that legitimate exceptions to list could be excluding a measure that is irrelevant to the managed care covered population in a state and a measure of the quality of a service not covered by, or relevant to, the managed care contract.*

*We **strongly disagree** with the preamble suggestion that a state might qualify for an exemption if it surpasses a defined threshold for multiple years. For many measures, such as certain vaccinations or the frequency of “never events,” a threshold of 90 percent would not be considered successful. Even if HHS set appropriate thresholds for each national measure, the exemption process leaves no mechanism to prevent against deterioration in performance after the exemption is granted – a deterioration that may go unnoticed because the state is no longer collecting data on that metric. Moreover, while the overall managed care population might exceed a given threshold; significant disparities may remain for important subpopulations. Allowing a state to then exempt its managed care entities from reporting that metric could thus undermine HHS’ broader efforts to identify and reduce health disparities across key demographic groups. If HHS were to go forward, against our recommendation, and allow this type of exemption, it should require that the threshold also demonstrate that no significant disparities exist and it should limit the exception to no more than two years.*

*We encourage HHS to clarify the relationship between the state and national measures and PIP topics selected under §438.330(a)(2) and the state measures selected under §431.502(b)(2). The proposed comprehensive quality strategy is meant to apply statewide across delivery systems; but it is unclear if the national measures selected under §438.330 for all managed care plans would also apply in the Medicaid FFS context, or if States could pick entirely different measures to apply to FFS.*

*We applaud HHS for requiring PCCM entities to establish and maintain mechanisms to detect over- and underutilization of services under §438.330(b)(3), like other managed care entities. Such mechanisms can be important tools to detect potential misuse, identify access barriers and evaluate network adequacy.*

*Paragraph (c)(4) requires that states contracting with MCOs, PIHPs or PAHPs to cover LTSS must develop additional metrics related specifically to the quality of LTSS. While we recognize that LTSS performance measurement, specific to both children and adults, is not well developed, this requirement will help advance better and more*

comprehensive metrics. We support the requirements in this provision to evaluate quality of life, rebalancing, and community integration. We urge HHS to also require states to include measures related to care coordination and the needs assessment process, in states that implement this option.

**Recommendation:** Amend §438.330(a)(2) as follows: HHS, through a public notice and comment process in consultation with States and other stakeholders, may specify performance measures, **for both pediatric and adult populations**, for collection in accordance with paragraph (c) of this section, a methodology for calculating quality ratings, and topics with performance indicators for performance improvement projects in accordance with paragraph (d) of this section to be required by States in their contracts with MCOs, PIHPs, and PAHPs.

**Recommendation:** Amend §438.330(a)(2)(ii) as follows: A State may apply for an exemption, **for no more than 2 years**, from collecting and reporting on the performance measures or performance improvement projects established under (a)(2) of this section, by submitting a request, in writing, to HHS which details the reason, **as described in (A) and (B)**, for such an exemption.

**Recommendation:** Add limited reasons for which a state may receive an exemption at §438.330(a)(2)(ii) as follows: **(A) if the measure is not applicable to the covered population; or (B) if the measure is only relevant to a service or services not covered in the MCO contract.** If HHS, against our recommendation, permits exemptions based on sustained achievement, the thresholds must be appropriate for each measure and states should have to prove that no significant disparities exist for key demographic groups prior to receiving a time-limited exemption.

**Recommendation:** Amend paragraph (c)(4) as follows: LTSS performance measurement. The State must require, through its contracts, each MCO, PIHP, and PAHP that provides LTSS services to include, as a part of its performance measurement activities under this paragraph and in addition to other measures required of all MCOs, PIHPs, and PAHPs, measures that assess the quality of life of **both pediatric and adult** beneficiaries, **the timeliness and effectiveness of the needs assessment process, the efficacy of care coordination measures** and the outcomes of the MCO, PIHP, or PAHP's **activities related to rebalancing, self-direction of services (if applicable),** and community integration activities for beneficiaries receiving LTSS.

#### §438.332 State review and approval of MCOs, PIHPs, and PAHPs

Generally, we are not opposed to requiring that states develop specific accreditation standards for their contracted MCOs, PIHPs and PAHPs, provided that states solicit public comment in establishing those standards and subsequently make them readily available to the public. This proposed rule allows states to set their own review standards, but it seems much more likely that states will instead choose to deem compliance based on accreditation by an approved private independent entity. We have a number of significant reservations about this approach.

The process of setting standards for Medicaid and CHIP should include input from the public. But, the regulation does not include a mechanism allowing the public to review or provide input into what those standards actually are.

*The public should have access to the results of the actual accreditation survey and report, not just the final level of accreditation achieved by the plan, if the state accepts accreditation by private entities. Private accrediting entities, such as the National Committee for Quality Assurance (NCQA) and URAC, do not make their accreditation standards readily available to the public, sometimes claiming them to be “proprietary property.” While available for purchase, these standards may be quite expensive. Private entities’ standards and measures must be readily and publicly available at no or nominal cost, or should be determined by the state after a robust stakeholder engagement process.*

*The accreditation process should be specific to the Medicaid business line of a participating MCO, PIHP or PAHP, yet this rule does not specify this criterion. Medicaid populations are different from commercial groups and have unique needs. If states are allowed to use an MCO-wide accreditation standard, it may not be a reliable predictor of how well that MCO will be prepared to manage care for Medicaid populations, especially with regards to children with special health care needs or LTSS, which have not historically been a focus for managed care companies and are not covered under typical commercial or Marketplace insurance plans. Accreditation should accordingly be specific to the Medicaid business line and should be adapted to incorporate state-specific standards as well as considerations that adhere to the unique needs of Medicaid populations.*

*Accreditation should not undermine other quality assurance efforts. The proposed rule’s expansion of required accreditation, which is written to strongly encourage states to make use of private accrediting agencies, could easily end up replacing many, if not most, of the key elements of EQR, and perhaps in a less timely, less accountable and less effective manner. We **strongly oppose** the proposal to expand EQR nonduplication exceptions to allow information gathered from private accreditation entities to be used in lieu of the validation of performance improvement projects and performance measures due to concerns about timeliness, transparency, the independence of accreditation validators and the vagueness of the “substantially comparable” standard in proposed §438.360. See discussion of §438.360 below for more detail.*

**Recommendation:** Amend §438.332(b) as follows: Compliance deemed on the basis of accreditation by a private independent entity. (1) The State may elect to use proof of MCO, PIHP, or PAHP accreditation by a private independent entity recognized by HHS under 45 CFR 156.275(c) or approved under §422.157 of this chapter to satisfy the requirement described in paragraph (a) of this section **if it is specific to the Medicaid population.**

**Recommendation:** Amend §438.332(b)(2)(i) as follows: Accreditation status, survey type, or level (if applicable) **and the standards and measures used.**

*§438.334 Medicaid managed care quality rating system*

*We understand the potential value of a robust and well-designed quality rating system for Medicaid managed care plans. Such tools can provide consumers with user-friendly information that can help them make informed selections from a variety of options. A quality rating system can also encourage transparency and even strengthen the oversight process. However, a poorly designed or executed quality rating system can*



*do quite the opposite by potentially giving plans an undeserved imprimatur of excellence.*

*Any effective quality rating system must include a transparent process for addressing the demographic differences between covered populations for different plans. On the one hand, if a plan does a particularly good job with care management for chronic conditions and attracts more individuals with chronic conditions, its performance on health outcome measures may actually go down relative to another plan that serves a healthier population. On the other hand, if a plan knows its quality outcomes will be risk adjusted to account for sicker members, it may have less incentive to focus on improving outcomes for those individuals. In either case, there must be a clear and transparent process for addressing risk adjustment for any Medicaid quality rating system. This will be particularly important should a state (or HHS) decide to implement or apply a similar system to its FFS populations.*

*It is unclear what HHS means by “affordability” in subparagraph (a)(2)(iii). Out-of-pocket expenses for Medicaid beneficiaries do not vary by health plan, so we interpret this phrase to mean “affordability” in terms of overall costs to the Medicaid program. While this may be an important goal for the State agency, it is not strictly relevant to the quality of care offered by a health plan, and may in fact run counter to the aims of a quality rating system intended for consumer use. For example, if affordability factors into a plan’s rating, one would expect that a plan that is cheaper for the Medicaid program may rate equally to a slightly more expensive plan with better health outcomes. From the point of view of a beneficiary, the second plan would be the better choice, but the quality rating system might not reflect that. We believe the term “efficiency” better addresses the triple aim of better care, better health outcomes, and affordability. We recommend that HHS delete “affordability” as a component of the quality rating system (unless affordability specifically refers to the individual’s ability to pay out-of-pocket expenses).*

*Finally, the preamble discusses the elements of a public comment and stakeholder engagement process to design and implement the quality rating system. HHS should ensure that detailed requirements for this process are clearly outlined in the regulation. The proposed regulation refers only to the federal public process for determining which measures are required and how that data will be collected. That public comment process does not include how the different measures will be weighted in an overall quality rating system, nor how States will account for differences in covered populations between plans. The regulations should clearly indicate how such key elements would be included in the federal (or state) stakeholder process. In addition to looking at CCIIO’s public engagement approach, we urge HHS to model this process after the transparency and public engagement requirements for the §1115 demonstration approval process. Without clear regulatory language, key stakeholder engagement and buy-in will likely be lost in the planning process. Certainly, the regulations should require any state that elects to design an alternative process to engage in a robust public comment process before receiving HHS approval.*

**Recommendation:** Amend paragraph §438.334(a)(2) as follows: The quality rating system must be based on the following ~~three~~ **four** components:

- (i) Clinical quality management **and, if applicable, management of LTSS.***
- (ii) Member **and provider** experience.*

**(iii) Enrollee access to care**

~~(iii)~~ **(iv) Plan efficiency, affordability, and management.**

**Recommendation:** Add a new paragraph (a)(4) to ensure consumers will understand how to use the tool: **The State must conduct sufficient outreach, notice and education to ensure that users can readily identify and understand the strengths and limitations of the rating system, including but not limited to information on how LTSS factors into the rating and how the rating system weights plan ratings based on enrollment demographics.**

**Recommendation:** Amend paragraph (c) to require states that elect to develop an alternative rating system to establish a robust stakeholder engagement and public comment process similar to the requirements for §1115 demonstrations as follows: (c) Alternative quality rating system. Upon HHS approval, a State may opt to use an alternative quality rating system that utilizes different components than those described in paragraph (a)(2) of this section, incorporates the use of different performance measures than those described in paragraph (a)(3) of this section, or applies a different methodology from that described in paragraph (b) of this section. **HHS will not approve such an alternative system unless the state's proposal has satisfied public comment, notice and consultation requirements at least as stringent as those for §1115 demonstration projects described in 42 C.F.R. §431 Subpart G. States must include evidence of consultation with the state MCAC, the state LTSS stakeholder advisory group, and other stakeholders, including health consumer advocacy coalitions in the state and representatives of both the pediatric and adult populations.**

§438.340 Managed care elements of the State comprehensive quality strategy  
We support the additional elements HHS has proposed requiring states to include in their CQS. We ask HHS to clarify the relationship between the state-selected quality metrics described in §431.502(b)(2) and the state-selected metrics described in §438.330(a)(2)(i). Additionally, it is not clear whether or how metrics selected in the HHS public comment process described in §438.330(a)(2) would apply to a state's Medicaid FFS system.

**Recommendation:** Clarify the relationship between the metrics described in §431.502(b)(2) and those in §438.330(a)(2).

### **§457.1250 External quality review**

The preamble regarding §457.1250 seeks comment regarding the proposed policy that funding for CHIP quality activities would be limited to the 10 percent administrative expenditures allotted for non-primary services in §457.618. We recognize that HHS has limited authority to expand the types of services that qualify as child health assistance under section 2105(a)(1)(A) and (C), but we believe that HHS should consider whether quality activities could be considered a primary service under §457.618 and thus accounted for outside of the 10 percent administrative limit. The treatment of quality services under the MLR provision provides a useful analogy as to why quality activities

should be considered a primary service accounted for outside of the 10 percent limit. In the MLR provision at §438.8, as applied to CHIP at §457.1205, quality-related activities are part of the numerator, suggesting that they are more closely linked to claims than to administrative expenses. If HHS is unable to allow states to account for CHIP quality expenses outside the 10 percent administrative cap, then HHS should closely monitor the impact of additional quality spending on CHIP programs, particularly for small states for which adding these services under the ten percent administrative cap will be more difficult. We also commented on the EQR sections in Medicaid, and we repeat those comments here for easy reference.

#### *§438.350 External Quality Review*

*HHS has proposed several very positive changes for Medicaid EQR. We support the proposal to extend EQR to include PAHPs that contract with the state, to increase EQR availability, and especially the proposal to add a new mandatory EQR-related activity focusing on actively testing MCO, PIHP and PAHP managed care networks. On the other hand, HHS appears to have simultaneously weakened EQR through the broadening of the nonduplication provision in §438.360 and the reduction of federal matching rates for EQR and EQR-related activities conducted on non-MCO managed care plans. We describe these concerns below.*

*Notably, the EQR may be appropriate for certain PCCM entities that participate in shared savings, incentive payments, or other arrangements for financial reward for improved quality outcomes, per §438.3(r). With the rapid evolution and hybridization of delivery systems, such models must also be accountable for delivering quality care, and EQR review is one appropriate approach. We do not agree with the proposed language that states should have sole discretion over whether EQR should be required for such PCCM entities. We believe the regulation should presume that PCCM entities with a financial stake in quality outcomes would be subject to EQR, and that the state should have to justify not requiring EQR for such PCCM entities to the Secretary. At the very least, we recommend amending the proposed language to clearly give the Secretary the option to require EQR for such entities.*

*We also propose clarifying language in paragraph (a)(3) to indicate that information obtained from private accreditation or Medicare can only be used if the applicable requirements have been satisfied.*

***Recommendation:*** *Add the following language to paragraph (a)(3): The information used to carry out the review must be obtained from the EQR-related activities described in §438.358 or, **if applicable**, from a Medicare or private accreditation review as described in §438.360.*

***Recommendation:*** *Add the following language to paragraph (b): **Consistent with the requirements of §438.3(r),** Aa State ~~may~~ **must** require that a qualified EQRO performs an annual EQR for each PCCM entity **with a State contract that provides for shared savings, incentive payments or other financial reward for improved quality outcomes, unless the State provides written evidence that EQR would be inappropriate for such entity and the Secretary approves the exemption** ~~consistent with the requirements of §438.3(r).~~ If an EQR is performed, the requirements...*

#### *§438.354 Qualifications of external quality review organizations*

While this section is largely unchanged from the current regulations, we recommend adding language to the independence protections to ensure that an organization with ties to an MCO, PIHP, or PAHP may not qualify as an EQRO to review competitors in the same service area. We believe this closes a potential loophole in the independence protections.

We suggest that, because EQR may be required of certain PCCM entities, the independence provision also list controlling relationships with PCCM entities as a disqualifying factor for EQROs. We believe this simply corrects a drafting oversight and reflects the intention of HHS' proposed changes. Similar additions may also be appropriate for other sections in the EQR regulation.

We support the prohibition that entities that conduct accreditation reviews on contracting MCOs, PIHPs, PAHPs, or PCCM entities may not perform as EQROs.

**Recommendation:** Throughout subsection (c) add "PCCM entity" to the list of managed care organizations, such that "MCO, PIHP, or PAHP" becomes "MCO, PIHP, PAHP, or PCCM entity."

**Recommendation:** Add the following language to subparagraph (c)(3)(i), stating that an EQRO may not: (i) Review a particular MCO, PIHP, ~~or PAHP~~, **or PCCM entity, nor review any other MCO, PIHP, PAHP or PCCM entity operating in the same service area as such particular MCO, PIHP, PAHP, or PCCM entity**, if either the EQRO or the MCO, PIHP, or PAHP, or PCCM entity exerts control over the other (as used in this paragraph, 'control' has the meaning given the term in 48 C.F.R. §19.101) through—

**Recommendation:** Add the phrase "or expected" to subparagraph (c)(3)(v), stating that an EQRO may not: (v) have a present, ~~or known~~ **or expected** future, direct or indirect financial relationship with an MCO, PIHP, ~~or PAHP~~, **or PCCM entity** that it will review as an EQRO.

#### §438.356 State contract options for external quality review

We support the contract options provision as written, including the requirement that states follow an open, competitive procurement process. The regulations at 45 C.F.R. 75 require that each Request for Proposals (RFPs) be publicized, but does not specify that states post RFPs on the state Medicaid website. We also strongly recommend that the public have a role in reviewing and commenting on the details of the RFP.

**Recommendation:** Add the following sentence to §438.356(e): For each contract with an EQRO described in paragraph (a) of this section, the State must follow an open, competitive procurement process that is in accordance with State law and regulations. In addition, the State must comply with 45 C.F.R. Part 75 as it applies to State procurement of Medicaid services.

**Notwithstanding State law, the State agency shall post its Request for Proposals on a website that is accessible to the public and provide a reasonable public comment period prior to beginning the bidding process.**

#### §438.358 Activities related to external quality review

As Medicaid increasingly employs capitation and accountable care as the preferred payment model, robust, independent quality review becomes an even more critical component to counteract financial incentives to limit coverage of necessary care. To this end, we commend HHS for proposing to require EQR to include validation of provider network adequacy. The preface suggests this new EQR protocol will include

*direct testing methods such as secret shopper surveys, to validate network adequacy for MCOs, PIHPs, PAHPs and PCCM entities required to conduct EQR under §438.350. The 2014 HHS Office of the Inspector General (OIG) reports cited in the preamble demonstrate the efficacy and importance of directly evaluating provider networks for compliance, access and availability. They plainly show that the “compliance reviews” normally conducted through EQR can be pro forma and have not effectively evaluated actual compliance in the area of network adequacy. Moreover, states that engage in direct testing of compliance, such as calling providers to assess availability and verify the accuracy of provider directories, or calling plan customer service to evaluate wait times and responsiveness, are far more likely to identify violations in access and timeliness standards.*

*We support HHS’ imposition of the requirement to validate network adequacy, but believe it should be strengthened. As the OIG reports revealed, an absence of violations of requirements can indicate a weak and passive review process rather than exceptional plan performance. We believe it unlikely that managed care compliance problems are limited to provider networks. For this reason, we recommend that HHS expressly require direct testing in other compliance areas as well, including care coordination, utilization management, and service authorization. Under our recommendation, a state would have to conduct annual direct testing of at least a subset of managed care quality standards each year. This requirement would stand apart from the existing requirement to require comprehensive compliance review at least every three years. Parameters for how states or HHS would prioritize areas for direct testing under this provision could be determined through subregulatory guidance. We also recommend that the annual EQR technical report include an accounting of all violations identified by the state or EQRO during the compliance review and explain corrective actions taken.*

*The provision requiring validation of network adequacy should also be strengthened. First, while the preamble explains that direct testing will be described in future guidance detailing the network adequacy validation profile, this oversight technique is important enough that it should be expressly described in the regulation itself. Second, HHS should clarify that the validation of network adequacy includes three interrelated but distinct components: network adequacy standards (which must include at least time and distance standards), timeliness and availability standards (described in detail in §438.206), and the accuracy of provider directories (described in §438.10(h)). As currently written, the EQR would only have to validate State network adequacy standards required in §438.68, and it does not clearly encompass the other two fundamental components. HHS’ description of the proposed new EQR protocol does envision activities such as testing provider directories, but the preamble also appears to distinguish the requirements at §438.206 from network adequacy standards when it claims that: “An assessment of compliance with §438.206 (availability of services) would occur as part of the mandatory compliance review described in §438.358(b)(3).” However, that review occurs only once in three years, not annually. An external reviewer should measure provider accessibility and timely availability annually because it is fundamental to ensuring that enrollees can find a provider and get the services they need when they need them. We strongly recommend that HHS revise the provision requiring validation of network adequacy to cross reference §438.206 and*

*§438.10(h) along with §438.68. These include precisely the sort of protections that direct testing should evaluate.*

*Finally, we recommend that HHS add two mandatory EQR activities. We believe a full review and accounting of grievances and appeals should be a mandatory EQR-related activity. Such a review can provide states with another mechanism to identify systemic issues and act upon them. Similarly, requiring states or EQROs to collect data directly from enrollees, in the form of focus groups or beneficiary surveys, will provide a useful cross check for broad-based CAHPS surveys and can help states directly evaluate a plan's compliance with other standards, such as care coordination and utilization management. Such consumer surveys and focus groups are currently optional EQR-related activities.*

**Recommendation:** Amend §438.358(b) as follows, including PCCM entities at paragraph (3), adding a new paragraph (4) (renumbering (b)(4) to (b)(5)), moving paragraph (c)(2) to (b)(6), and adding new paragraph (7):

*(3) A review, conducted within the previous 3-year period, to determine the MCO's PIHP's, ~~or~~ PAHP's, or PCCM entity's compliance with the standards set forth in subpart D and the quality assessment and performance improvement requirements described in §438.330.*

**(4) Validation by direct testing of compliance with at least a subset of the standards set forth in subpart D and the quality assessment and performance improvement requirements described in §438.330 during the preceding 12 months.**

~~(4)(5)~~ **(5) Validation of MCO, PIHP, ~~and~~ PAHP, and PCCM entity network adequacy during the preceding 12 months to comply with requirements set forth in §438.68, §438.206, §438.10(h) and §438.208(b) and (c). This validation must include direct testing of the plan's provider network through mechanisms such as secret shopper surveys or direct calls to network providers to evaluate availability and accessibility.**

**(6) Administration or validation of quantitative and qualitative research with enrollees, such as consumer surveys and focus groups, conducted during the preceding 12 months examining consumer experience and care quality.**

**(7) A review and analysis of complaints, grievances, and appeals filed in the preceding 12 months with each MCO or PHP, including their outcomes, to identify systemic problems and recommend potential remedies.**

**Recommendation:** Strike paragraph (c)(2) to conform with the recommended changes as follows: ~~(c)(2) Administration or validation of consumer or provider surveys of quality of care;~~

*§438.364 External quality review results*

*We support the recommended additions that require EQR annual technical reports to include results from performance measures and from PIPs alongside the validation results. States are not currently required to report these results, though many already do. This change will make it easier to locate data by centralizing it in a single report that must be posted on the state Medicaid website. We also recommend that technical reports monitor compliance violations to make it easier to track and compile violations across plans and states. Such data was included in the OIG reports on network adequacy and helped show the value of direct testing in that context.*

*We also support the changes in this section that require states to post the annual EQR technical report on their Medicaid website. Because part of the EQR involves providing annual recommendations for improvement and evaluating how well plans have responded to prior recommendations over time, we recommend that HHS require plans to maintain an archive of past EQR technical reports on their Medicaid website. This represents minimal added burden for the state, but provides a much richer longitudinal perspective of how plans perform over time.*

**Recommendation:** *Add a requirement that EQR technical reports account for all violations identified by the state or EQRO during the compliance review and detail corrective actions taken.*

**Recommendation:** *Add language to the second sentence of paragraph §438.364(b)(2) to require states to create and maintain an archive of annual technical reports on its website, as follows: The state must make the most recent copy of the annual EQR technical report publicly available on the state's website required under §438.10(c)(3) **and maintain on such website an archive of prior technical reports dating back at least five years or to the inception of the State's managed care program.***

## **F. Grievances and Program Integrity**

### **§457.1260 Grievances**

We support the alignment of CHIP grievance provisions with Medicaid at §457.1260. We also concur with HHS that the references to fair hearings in subpart F of part 438 should be read as references to reviews for part 457. With respect to the application of §438.420 regarding benefits pending appeal, we believe that while alignment with Medicaid would be valuable for CHIP beneficiaries, the nature of the CHIP program merits different treatment. Thus we believe §457.1260 should be finalized as proposed.

### **Program integrity and program integrity safeguards**

We support aligning the managed care program integrity standards at §§457.1280 and 457.1285, but we note that there is an error in the regulatory text. These provisions are in subpart L, not subpart K.

We support the application of subpart H of part 438 to CHIP at §457.1285. We made some suggestions to §438.602 regarding transparency that we repeat here for easy reference.

*We support the requirement at §438.602(g) to promote transparency by requiring posting of certain documents and data. We believe the requirement at §438.602(g)(3) should be finalized as proposed, however we recommend some changes to §438.602(g)(1) and (2).*

**Recommendation:** *Amend §438.602(g)(1) to require posting of the managed care contracts rather than allowing the state to make them available upon request. Similarly, amend §438.602(g)(2) to specifically require posting of*

*certain elements under §438.604. Specifically, we recommend requiring posting of §438.604(a)(2) regarding data on the basis of which the state certifies the actuarial soundness of capitation rates, §438.604(a)(3) regarding data on the basis of which the state determines compliance with the MLR requirement, and §438.604(a)(5) regarding documentation described in §438.207(b) related to availability and accessibility of services.*

*If HHS is unable to require such posting, we recommend that HHS specify the timeframe by which the state must provide the information on request, such as within ten days.*