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July 27, 2015

VIA ELECTRONIC SUBMISSION

Victoria Wachino
Director, Center for Medicaid and CHIP Services
Centers for Medicare & Medicaid Services
U.S. Dept. of Health and Human Services
7500 Social Security Blvd.
Baltimore, MD 21244-1850

RE: CMS-2390-P

Dear Ms. Wachino:

Thank you for the opportunity to comment on HHS' proposed regulations on Medicaid and CHIP managed care published on June 1, 2015 (80 Fed. Reg. 30198). The National Health Law Program (NHeLP) protects and advances the health rights of low income and underserved individuals. The oldest non-profit of its kind, NHeLP advocates, educates and litigates at the federal and state level.

We greatly appreciate these efforts to update and improve the regulations and we strongly support many of the proposed changes. We also have concerns about others and have recommendations about how the proposed regulations could be improved. A summary of our proposed changes appears at the beginning of our in-depth comments.

Thank you for your attention. If you have any questions or need any further information, please contact Sarah Somers, Managing Attorney (somers@healthlaw.org; (919) 968-6308 ext 102), at the National Health Law Program.

Sincerely,

Elizabeth G. Taylor,
Executive Director

NATIONAL HEALTH LAW PROGRAM

COMMENTS ON PROPOSED MEDICAID AND CHIP MANAGED CARE REGULATIONS

NHeLP
NATIONAL HEALTH LAW PROGRAM

SUMMARY OF COMMENTS ON
PROPOSED MEDICAID AND CHIP MANAGED CARE REGULATIONS

NHeLP particularly supports the following proposals:

- Providing for continuation of benefits pending appeal regardless of whether an authorization period has expired to protect beneficiaries from disruption in needed care (§ 438.420);
- expanding requirements to ensure continuity of care for beneficiaries (§ 438.54);
- providing for continued services during times of transition between managed care and FFS (§ 438.62);
- addition of requirements governing network adequacy for all services, including LTSS, particularly the requirement that states establish time and distance standards for specified services (§ 438.68);
- requiring plans to comply with the EPSDT requirements of the Medicaid Act and prohibiting contractual definitions of medical necessity narrower than those used in states' Medicaid programs (§ 438.210(a));
- expansion of the requirements of the state comprehensive quality strategy (CQS) to include Medicaid fee-for-service delivery (FFS) (§ 431.502);
- expansion of antidiscrimination requirements to additional protected classes and the incorporation of the requirement to comply with § 1557 of the ACA (§ 438.3);
- application of Medicaid FFS Drug Utilization Review (DUR) activities to the Medicaid managed care prescription drug benefit and increase in prescription drug formulary transparency (§§ 438.3(s); 438.10(i));
- addition of specifications regarding actuarially sound rates, including increased transparency and the requirement to submit rate certifications (§§ 438.4-438.7);
- establishing medical loss ratio (MLR) calculation and reporting requirements (§ 438.8);
- application of additional requirements to PAHPs, particularly the requirement to maintain a grievance system;
- expanding requirements governing provision of information about Medicaid managed care, including the obligation to make information available through a state Web site (§ 438.10);
- requiring states to develop state-level LTSS stakeholder advisory committees and a beneficiary support system (§§ 438.70, 438.71);

- applying many of the quality monitoring requirements to PAHPs and PCCM entities (Subpart E); and
- introducing a Medicaid managed care star rating system (§ 438.334).

NHeLP does not support the following proposals:

- Requiring that enrollees exhaust internal plan appeals (§ 438.402);
- including unpaid cost sharing amounts in the premium revenue component of the MLR denominator (§ 438.8(f)(2)(iv));
- allowing states to pay capitation payments to plans for months in which enrollees have a short stay in an IMD (§ 438.3(u));
- exempting of NEMT-PAHPs from many requirements, including the requirement to maintain a grievance system (§ 438.9);
- allowing states to establish their own definition of a "prevalent" language (§ 438.10); and
- allowing states to deem plan compliance with EQR based on accreditation by an approved private independent entity (§ 438.332).

We believe that there is room for improvement, particularly by taking the following steps:

- Amending the provisions governing authorization of services and continuation of benefits to ensure that authorization practices do not result in interruption of services (§ 438.210, 438.420);
- providing additional safeguards to ensure that beneficiaries have the ability to choose a managed care entity and access to providers that will meet all of their reproductive health needs (§§ 438.52, 438.68, 438.102, 438.210; 438.230);
- requiring more specificity regarding expedited appeals (§ 438.408);
- requiring states to adopt specific network adequacy requirements (§438.68);
- providing for exemption from managed care enrollment (§ 438.54);
- adding additional reasons for disenrollment for cause (§ 438.56);
- adding requirements listing services plans must provide to ensure language access and accessibility for individuals with disabilities;

- clarifying that a enrollee cannot be charged for family planning services and supplies and family planning-related services that are covered by the State plan when obtained out-of-network (§ 438.106);
- requiring plans to disclose the process they and their contractors use to authorize coverage of services, including LTSS (§ 438.201);
- amending the definition of "quality" to include more than medical health (§ 438.320);
- requiring direct testing as a part of quality review (§ 438.320);
- limiting the reasons for exemptions from quality review (§ 438.330);
- requiring a full review and accounting of grievances and appeals as a mandatory EQR-related activity (§ 438.358);
- requiring the MCOs, PIHPs, and PAHPs to maintain records, on a quarterly basis, of the total number of grievances and of the total number of appeals, and for appeals (§ 438.416); and
- provision for a de novo hearing.

NATIONAL HEALTH LAW PROGRAM

PART 431

§ 431.205 - Provision of hearing system

Section 1557 of the Affordable Care Act (ACA) updated and expanded civil rights requirements for the Medicaid program. While we provide suggestions throughout our comments regarding the need to ensure access for individuals who are limited English proficient and individuals with disabilities, we also strongly believe that HHS should update § 431.205 to specifically require accessibility for persons who are LEP or have disabilities in the fair hearing process. While we recognize that § 431.205 was not part of the proposed revisions in the published Notice of Proposed Rulemaking (NPRM), we still believe that given the enactment of § 1557 and the need to ensure access broadly, HHS has the authority to amend § 431.205 to include reference to the need to ensure access and comply with existing civil rights laws.

RECOMMENDATION: Amend § 431.205 as follows:

> § 431.205 Provision of ***notice and*** hearing system.
>
> (a) The Medicaid agency must be responsible for maintaining a ***notice and*** hearing system….
>
> (d) The ***notice and*** hearing system must meet the due process standards set forth in *Goldberg v. Kelly*…
>
> (e) ***The notice and hearing system must, at no cost to the individual:***
>
> (1) ***ensure the provision of auxiliary aids and services to individuals living with disabilities in accordance with the Americans with Disabilities Act, section 504 of the Rehabilitation Act, and Section 1557 of the Affordable Care Act; and***
> (2) ***ensure that the system is accessible to individuals who are limited English proficient in accordance with Title VI of the Civil Rights Act of 1964 and Section 1557 of the Affordable Care Act through the provision of competent language services.***

We have made further recommendations to changing part 431 in our discussion of part 438, subpart F. See p 153, below.

§ 431.502 - State comprehensive quality strategy

We strongly support HHS's proposal to extend the requirements of the state comprehensive quality strategy (CQS) beyond managed care to include Medicaid fee-for-service delivery (FFS) as well. 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 Web site.

In § 431.502(b)(1), HHS proposes that each state's CQS must lay out goals and objectives to "take into consideration the health status of all populations served by the Medicaid program." We suggest that CMS add language to ensure that "health status" is understood broadly to include mental health, functional status, and quality of life in the community as well.

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 Affordable Care Act 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.[1] It is also important to collect information about individuals based on age. 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. Stratifying quality data by the key factors called for in the ACA would sharpen quality improvement interventions, identify groups that continue to be left behind, and provide a status report on whether managed care is helping to resolve the longstanding inequities in our health care system.

We appreciate that HHS has active programs, such as the Adult Medicaid Quality Grants Program, to help states build their capacity to collect and report data stratified by key demographic categories.[2] HHS has also produced reports with recommendations on how to improve data collection on health disparities in Medicaid and CHIP.[3] Health

[1] 42 U.S.C. § 300kk (codifying ACA § 4302(a)).
[2] *Adult Medicaid Quality Grants Program*, CMS, http://medicaid.gov/medicaid-chip-program-information/by-topics/quality-of-care/adult-medicaid-quality-grants.html (last visited July 8, 2015).
[3] KATHLEEN SEBELLIUS, HHS, REPORT TO CONGRESS: APPROACHES FOR IDENTIFYING, COLLECTING, AND EVALUATING DATA ON HEALTH CARE DISPARITIES IN MEDICAID AND CHIP (2011), *available at* http://www.medicaid.gov/medicaid-chip-program-information/by-topics/quality-of-care/downloads/4302b-rtc.pdf; SILVIA MATTHEWS BURWELL, HHS, REPORT TO CONGRESS: IMPROVING THE IDENTIFICATION OF HEALTH CARE DISPARITIES IN MEDICAID AND CHIP (2014), *available at* http://www.medicaid.gov/medicaid-chip-program-information/by-topics/quality-of-care/quality-of-care-health-disparities.html.

disparities are, however, mentioned just once in these proposed regulations and only in the context of network adequacy, not quality measurement.[4] We urge HHS to take advantage of this opportunity to advance the requirements of the Affordable Care Act and ensure that states develop quality measurement programs with the capacity to evaluate health disparities and take the necessary steps to eliminate them.

RECOMMENDATIONS: Amend § 431.502(b)(1) to reflect 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.

Add 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 race, ethnicity, sex, primary language, geography, age, and disability status and actions taken to reduce health care disparities.***

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

We support HHS's 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 CMS 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, such as HCBS settings transition plans, we have seen states bury hearing and comment notices in obscure locations on their website, produce draft plans so lacking in detail that no meaningful comment is possible, or submit to CMS "revised" drafts after public comments that include not a single change to the original proposal. To avoid such problems and ensure meaningful stakeholder

[4] *See* 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 80 Fed. Reg. 31146 (June 1, 2015).

engagement in the proposed CQS drafting process, we urge HHS 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 CMS.[5] In addition, stakeholders have another 30-day comment period at the federal level for the revised draft. CMS 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 prominently 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 CMS (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:

(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 CMS for review. ***As part of such public comment process, the State must:***

(A) prepare a comprehensive draft of the comprehensive quality strategy that contains a sufficient level of detail to ensure meaningful input from the public

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

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

[5] 42 C.F.R. § 431.408.

(ii) the locations and Internet address where copies of the draft quality strategy are available for public review and comment;
(iii) postal, Internet 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
(iv) the location, date, and time of the State public hearings described in subparagraph (G) to seek public input on the demonstration application.

(C) publish and keep current its public notice process, public input process, schedule of planned hearings, and the draft quality strategy in a prominent location on either the main page of the public Web site of the State Medicaid agency or on a quality strategy-specific Web page that is linked in a readily identifiable way to the main page of the State agency's Web site throughout the comment and review process;
(D) 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 Web site

(i) 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 CMS, and
(ii) 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 quality strategy to CMS;

(E) utilize additional mechanisms, such as an electronic mailing list, to notify interested parties of the comprehensive quality strategy;
(F) at least 20 days prior to submitting the quality strategy to CMS for review, conduct 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; and
(G) provide in its submission to CMS a response to comments collected and to input received from the MCAC, the LTSS stakeholder committee, tribes and other stakeholders. The states response must include revisions made related to those comments and must be posted on the public Web site of the State Medicaid agency.

SUBPART A

§ 438.2 - Definitions

a. Primary Care Case Management Entity

In general, we support HHS' decision to add a new definition for PCCM entities. As states have expanded the care coordination and administrative functions of the PCCM, it is appropriate and necessary for HHS to adopt additional standards to govern these more complex entities.

We commend HHS for noting that PCCM entities may have some of the financial incentives as capitated entities. Accordingly, it is crucial that HHS and state Medicaid agencies exercise stricter control and increase monitoring of these entities. To this end, we strongly support HHS' decision to make these entities subject to increased monitoring and EQR requirements, as discussed below.

It is helpful that HHS has referenced SMDL #12-002 and noted that not all PCCM programs – such as integrated care models, accountable care organizations (ACOs), and the like – are subject to part 438 requirements.[6] This discussion and the use of the acronym "PCCM" is somewhat confusing, however, given that PCCMs are expressly defined in 438.2. We recommend that CMS clarify that entities that meet the definition in § 438.2 of PCCMs or PCCM entities *are* subject to part 438, while entities that may have some of the hallmarks of PCCMs (like ACOs) are not necessarily subject to part 438 if they do not constrain free choice.

Not only is this part of the preamble potentially confusing, the growing universe of integrated care models is creating uncertainty. Notably, there is no statutory or regulatory definition of a Medicaid ACO, despite the fact that many states are providing services through these entities. Thus, we urge HHS to engage in further rulemaking to fully explain the differences between integrated care models that are and are not covered by part 438.

Moreover, there is a growing need for a specific definition of ACOs. They are becoming increasingly prevalent in state Medicaid programs. According to the Center for Health Care Strategies (CHCS), nine states have active Medicaid ACO programs and at least seven are actively pursuing them.[7] Some of these ACOs are reporting promising results. It is likely, therefore, that these existing programs will expand and additional states will pursue their own ACO projects. Therefore, we encourage HHS to create a specific definition for Medicaid ACOs.

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[6] 80 Fed. Reg. at 31163.

[7] CTR. FOR HEALTH CARE STRATEGIES, MEDICAID ACCOUNTABLE CARE ORGANIZATIONS: STATE UPDATE (2015), *available at* http://www.chcs.org/media/ACO-Fact-Sheet-76151.pdf.

b. Other new definitions

We support broadening the definition of health care professional to include any provider whose services are covered under a managed care contract. This is preferable to attempting to list all of the providers whose services could be covered.

We support the addition of the services of "other licensed practitioner" to the definition of "primary care." As the health care system evolves and primary care services are provided by different types of health care professionals, it is necessary that the Medicaid managed care system be modernized to reflect this reality.

c. Definition needed for LEP

In addition, we recommend that HHS add a definition of "LEP." The term is used in §§ 438.10 and 438.420, but is not defined. Given that HHS (and DOJ) have articulated a definition, it should be used. Including it in this definitional section would promote consistency.

RECOMMENDATION: Amend § 438.2 as follows:

§ 438.2 - Definitions

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 the expansion of inspection and audit rights in § 438.3(g) and the requirement to submit audited financial reports

a. Antidiscrimination

We welcome the new reference to § 1557 of the ACA. While it is clear that § 1557 applies to Medicaid MCOs, PHPs, and all types of PCCMs, adding it to the regulations will help emphasize and publicize the new requirement.

We enthusiastically support HHS' decision to expand the anti-discrimination prohibition. 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 (in enrollment, covered and excluded services, medical necessity definitions, or utilization controls), provider refusals, or treatment avoidance due to perceived discrimination in treatment.[8]

Lesbian, gay, bisexual, and transgender (LGBT) individuals are more likely than the general population to lack health insurance coverage.[9] LGBT individuals with insurance too often struggle to find a culturally competent provider.[10] The proposed anti-discrimination provision banning discriminatory practices is a necessary step towards ensuring access to quality, culturally competent care.

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 may not be specifically covered by other provisions, but still have a strong adverse effect. This could include instances such as when managed care entities treat enrollees with disabilities who have high service needs or are difficult to deal with poorly in an effort to get such individuals to switch managed are entities.

b. Primary Care Case Management Entities

We strongly support HHS's decision to require PCCM entities to comply with performance measurement, quality standards, and EQR when their contracts provide for shared savings or other financial rewards for improved quality. As HHS notes, these entities have important features in common with MCOs and PHPs, including the financial incentive to limit coverage of necessary services. It is therefore appropriate to subject them to higher scrutiny.

We approve of the decision to require MCOs, PIHPs, PAHPs, and their subcontractors to retain certain records for six years. We wholeheartedly agree with HHS that such retention will aid monitoring and oversight – in fact, we believe that it is indispensable.

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[8] *See* INST. OF MED. OF THE NAT'L ACADS., THE HEALTH OF LESBIAN, GAY BISEXUAL, AND TRANSGENDER PEOPLE: BUILDING A FOUNDATION FOR BETTER UNDERSTANDING 234 (2011).
[9] JAIME M. GRANT, PH.D. ET AL., INJUSTICE AT EVERY TURN: A REPORT OF THE NATIONAL TRANSGENDER DISCRIMINATION SURVEY 76-77 (2011).
[10] *See* Laura R. Redman, *Outing the Invisible Poor: Why Economic Justice and Access to Care is an LGBT Issue*, 37 GEORGETOWN J. ON POVERTY LAW & POLICY 451, 457 (2010); INST. OF MED. OF THE NAT'L ACADS., THE HEALTH OF LESBIAN, GAY BISEXUAL, AND TRANSGENDER PEOPLE: BUILDING A FOUNDATION FOR BETTER UNDERSTANDING 226 (2011).

c. § 438.3(p) Health Insuring Organizations

We are concerned that this section does not clearly explain when HIOs are subject to the provisions of part 438, and when they are exempt. HHS did not make any substantive changes to this section, which is moved to § 438.3 from § 438.6. It seems that HHS originally added this section to explicitly require non-exempt HIOs to meet the requirements of MCOs in order to provide services to Medicaid enrollees on a comprehensive risk basis. *See* 67 FR 40989-01. This is consistent with the statute, which only exempts a narrow subset of HIOs from rules that apply to other capitated plans. HIOs that are not exempt by statute may still participate in Medicaid as managed care programs, but must meet the requirements of an MCO.[11] The definition in this section, however, includes only HIOs that are exempt by statute. Thus, by definition, any non-exempt HIO must qualify as an MCO in order to provide services to Medicaid enrollees on a comprehensive risk basis.

Moreover, we are concerned that the regulations do not clearly indicate when they apply to exempt HIOs and when they do not. The addition of this section only further muddies those waters. We are aware of instances where exempt HIOs have claimed that they are need not comply with any of the requirements in section 438 except where specifically mentioned in the regulatory text. We do not believe that this is HHS's intent; nor is it consistent with Congress's intent in establishing HIOs. Congress established HIOs with the intent of encouraging managed care in the Medicaid program; by exempting certain county-run plans from competition and licensure requirements that MCOs must meet, it allowed counties to establish plans that could meet the needs of their Medicaid enrollees. *See id*. 40989, 40994. But Congress never intended exempt HIOs to also be free from rules that other Medicaid plans must comply with related to providing accurate information to enrollees, ensuring their networks are adequate, or designing and implementing a grievance and appeals process that permits enrollees to complain about problems.[12] Rather, we understand HHS's intent is that exempt HIOs are subject to the same rules as other capitated managed care entities, except where exemptions specific to the HIO's special features apply. We suggest that HHS amend this section to omit reference to non-exempt HIOs, and instead clarify that exempt HIOs must meet all provisions of 438 except those to which they are explicitly exempted.

[11] H.R. REP. No. 99-727, at 124 (1986), reprinted in U.S.C.C.A.N. 3607, 3714 ("Section 9517(c) of COBRA clarified that where a [HIO] which has entered into a prepayment contract with a State does anything more than merely process claims for payment, it is subject to the same regulatory requirements as those to which any HMO or prepaid plan is subject under Medicaid law.").

[12] *See* Omnibus Reconciliation Act of 1981, ch. 2, sec. 2176, § 1915, 79 Stat. 286; Consolidated Omnibus Budget Reconciliation Act of 1985, Pub. L. No. 99-272, § 9517, 100 Stat. 82 (1986).

RECOMMENDATION: Amend § 438.3(p) as follows:

> § 438.3(p) *Special rules for ~~certain~~ HIOs*. Contracts with HIOs ~~that began operating on or after January 1, 1986, and that the statute does not explicitly exempt from requirements in section 1903(m) of the Act~~, are subject to all the requirements of this part that apply to MCOs and contracts with MCOs***, except where otherwise specified in this part***. These HIOs may enter into comprehensive risk contracts only if they meet the criteria of paragraph (a) of this section.
>
> *c. § 438.3(s) - Requirements for MCOs, PIHPs, or PAHPs that provide covered outpatient drugs.*

We support the application of Medicaid FFS Drug Utilization Review (DUR) activities to the Medicaid managed care prescription drug benefit. DUR can provide an effective tool, not only for program integrity, but to improve quality of care. However, DUR operations and standards provided under 42 U.S.C. § 1396r-8 are outdated and fail to provide enrollees with adequate protections and opportunities for engagement. We urge HHS to improve upon DUR requirements when applying them to Medicaid managed care.

DUR should be coordinated with and incorporated into quality and monitoring activities. For example, underutilization of prescription drugs, one of the concerns monitored by DUR, may indicate inadequate pharmacy inventories or access or overly burdensome prior authorization requirements. We recommend that HHS add drug utilization review to the ongoing state monitoring activities required in proposed § 483.66 and include DUR as part of the state's quality strategy and review process.

We also commend HHS for expressly requiring MCOs, PIHPs, and PAHPs to respond to prescription drug prior authorization requests within 24 hours, as well as provide for an emergency 72-hour supply of medications, as in FFS prescription drug coverage under 42 U.S.C. § 1396r-8(d)(5). We believe that these consumer protections are just as crucial for Medicaid managed care enrollees as for FFS beneficiaries. We also urge that these protections be recognized as the *minimum* required. In at least one state, Florida, the statutory requirements pertaining to the covered outpatient drug benefit (both in fee for service and managed care) are further defined pursuant to the terms of settlement in *Hernandez et al. v. Medows*, No. 02-20964 (S.D. Fla.). As noted in comments by our colleagues at Florida Legal Services, these requirements are more favorable to enrollees and should be maintained here – and in any other states that has protections more stringent than those proposed in these regulations.

As described in greater detail below, we are concerned that the proposed regulations apply an overly restrictive definition of "medically accepted indications" for approved drugs. The regulations should also expressly provide for an exceptions process to ensure that Medicaid enrollees can access non-formulary drugs and prescription

medications for off-label uses to more fully align Medicaid managed care regulations with requirements for plans providing Essential Health Benefits (EHB), including Qualified Health Plans (QHPs) sold through the Marketplaces.

We are also concerned that the proposed regulations have no minimum formulary or preferred drug list (PDL) requirements. The EHB standard probably is not applicable to some Medicaid MCO, PIHP, PAHP or PCCM entity enrollees. Therefore, we recommend that HHS apply protections for the six protected classes of drugs under the Medicare Part D program to Medicaid managed care, including the prohibition of step therapy for enrollees already taking a drug, and other onerous prior authorization requirements. Given that an increasing number of states are requiring persons with disabilities, seniors, and persons who are medically frail to enroll in Medicaid managed care, these same Part D protections, designed "to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations," should also apply.[13] Further, we note that the terms "formulary" and "PDLs" are often used interchangeably. Thus, we recommend that the rules specify that if a plan has a PDL (which is not defined in the statute) be subject to the same requirements as a "formulary," which is defined. See 42 U.S.C. §1396r-8(4)(C).

1. § 438.3(s)(1)

RECOMMENDATION: Add the following to § 438.3(s)(1):

> ***The MCO, PIHP, PAHP or PCCM entity (if applicable) that covers the six protected classes of drugs under Medicare Part D: immunosuppressants (for prophylaxis of organ transplant rejection), antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastic classes; shall not implement prior authorization or step therapy requirements within these classes for enrollees who are currently taking a drug. This prohibition applies to those beneficiaries already enrolled in the plan as well as new enrollees actively taking drugs in any of the six classes of clinical concern prior to enrollment into the plan. The MCO, PIHP, PAHP or PCCM entity (if applicable) must notify enrollees if it removes a drug from its formulary and provide information on the expedited and standard exceptions process required* under *§ 438.3(s)(7).***

2. § 438.3(s)(4)

We agree that Drug Utilization Review should apply to MCOs, PIHPs, and PAHPs, as well as PCCM entities, if applicable. The proposed rule requires each entity to operate its own separate Drug Utilization Review Board (DURB) in compliance with the requirements for state DURBs under 42 U.S.C. § 1396r-8(g). HHS should require

[13] *See* CMS, MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL, CH. 6, § 30.2.5 - PROTECTED CLASSES (2008).

DURBs to meet minimum transparency requirements, such as holding open meetings, publicly posting meeting agendas, and regularly consulting with the state's Medicaid Care Advisory Committee (MCAC) and LTSS stakeholder groups.

RECOMMENDATION: Add the following to § 438.3(s)(4) after the existing text:

> ***The MCO, PIHP, PAHP or PCCM entity (if applicable) shall make information on its review program publicly available, including meeting times, membership, educational programs, data on requests and coverage denials, and review reports. The MCO, PIHP, PAHP, or PCCM entity (if applicable) shall coordinate its review program activities with the state's Medical Care Advisory Committee authorized under 42 C.F.R. § 431.12, and the consumer stakeholder committees established pursuant to 42 C.F.R. § 438.70 and 42 C.F.R. § 438.110.***

3. § 438.3(s)(5)

As proposed, the managed care DURBs must report their activities annually to the state. Managed care DURBs should publicly post their annual reports and coordinate with the state DURB in reporting data and findings to CMS for analysis and reporting in its annual Medical Drug Utilization Review State Comparison and Summary Report.

RECOMMENDATION: Add the following language to § 438.3(s)(5) after the existing text:

> ***The MCO, PIHP, PAHP, or PCCM entity (if applicable) shall post to its website the annual report, and provide the report to the state DURB, MCAC, and the consumer stakeholder committees established pursuant to 42 C.F.R. § 438.70 and 42 C.F.R. § 438.110.***

4. § 438.3(s)(6)

We commend HHS for requiring MCOs, PIHPs, and PAHPs to respond to prescription drug prior authorization requests within 24 hours, as well as provide for an emergency 72-hour supply of medications, as in FFS prescription drug coverage under 42 U.S.C. § 1396r-8(d)(5). We further urge that this compliance with the statute be specified as a "minimum standard" pertaining to the statute's requirements for prior authorization and provision of an emergency temporary supply.

We are also concerned that proposed § 438.3(s)(6) unduly restricts off-label uses of medications. The proposed rule applies criteria under §1396r-8(k)(6) for "medically accepted indications" in the use of prescription drugs. These criteria limit off-label use of medications to only indications "included, or approved to be included" in any of three compendia: American Hospital Formulary Service Drug Information; United States Pharmacopeia-Drug Information (or its successor publications); or the DRUGDEX

Information System. We note that federal law requires Medicaid Drug Utilization Review Boards (DURB) to review drug usage under a broader standard than "medically accepted indications." The DURB considers not just uses under the three compendia, but also "peer-reviewed medical literature."[14]

Off-label drug use restrictions have been problematic in FFS Medicaid and should be curbed, not extended to Medicaid managed care. All three compendia are subscription based and charge considerable amounts for access, well beyond the means of most Medicaid enrollees. Moreover, the compendia are only periodically updated. For example, the US Pharmacopeia is updated every three years. HHS recognized the lag time in updating the US Pharmacopeia and other compendia in the HHS Notice of Benefit and Payment Parameters for 2016 Final Rule, 80 Fed. Reg. 10,750 (Feb. 27, 2015), now requiring P&T committees to supplement the Essential Health Benefit prescription drug standards (codified at 45 C.F.R. § 156.122).

Prescription drugs are increasingly prescribed for off-label uses that nonetheless meet prevailing standards of care and treatment guidelines supported by peer-reviewed medical literature. Undue restrictions on off-label uses of prescription drugs deprive Medicaid enrollees of potentially life-saving treatments available to persons in private plans.

We therefore recommend that HHS add a new sub-section (7) requiring a robust exceptions process to allow Medicaid managed care enrollees to obtain non-formulary prescription drugs when "clinically appropriate" and to allow off-label uses. The Medicaid managed care prescription drug benefit should align requirements for health plans subject to Essential Health Benefits (EHB) by providing an exceptions process that accommodates both standard requests and those made on an expedited basis.

The exceptions process should consider whether a non-formulary and off-label drug use is "clinically appropriate" by applying the broad standard for medical necessity outlined by HHS in its FAQS about Affordable Care Act Implementation (PART XXVI) (FAQ) (May 11, 2015). In this FAQ, HHS establishes a broad standard for allowing access to prescription contraception, considering side effects, adherence, and deferring to the judgment of the attending provider. HHS should apply the same standard to an exceptions process for all prescription drugs to provide strong protections for Medicaid managed care enrollees.

In addition, the exceptions process should not supplant the 72-hour emergency supply provided for under proposed 42 C.F.R. § 438.3(s)(5) and 42 U.S.C. § 1396r-8(d)(5), or a Medicaid enrollee's due process rights to notice and a fair hearing.

[14] *See* 42 U.S.C. § 1396r-8(g)(1)(B)(ii).

RECOMMENDATION: Add new sub-section (s)(7), as follows:

§ 438.3(s)(7) The MCO, PAHP, PHIP, or PCCM entity (if applicable) must have a process for an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to obtain a clinically appropriate drug that is not covered by the plan or for a use that does not meet the standard for medically accepted indications defined in 42 U.S.C. § 1396r-8(k)(6). A non-formulary drug or an off-label use that does not meet the standard for medically accepted indications defined in 42 U.S.C. § 1396r-8(k)(6) is clinically appropriate if its use is supported by the attending prescriber and (i) two articles from peer reviewed medical journals that present data supporting the proposed off-label use, or (ii) the use is generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal.

(i) An MCO, PAHP, PHIP, or PCCM entity (if applicable) must make its determination on a standard exception and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 72 hours following receipt of the request.
(ii) An MCO, PAHP, PHIP, or PCCM entity (if applicable) that grants a standard exception request must provide coverage of the non-formulary drug or off-label use for the duration of the prescription, including refills.
(iii) Expedited exception request. An MCO, PAHP, PHIP, or PCCM entity (if applicable) must have a process for an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request an expedited review based on exigent circumstances.
(iv) Exigent circumstances exist when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee's life, health or result in hospitalization or emergency room treatment, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a non-formulary drug or for a use that does not meet the standard for medically accepted indications defined in 42 U.S.C. § 1396r-8(k)(6).
(v) An MCO, PAHP, PHIP, or PCCM entity (if applicable) must make its coverage determination on an expedited review request based on exigent circumstances and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 24 hours following receipt of the request.
(vi) An MCO, PAHP, PHIP, or PCCM entity (if applicable) that grants an exception based on exigent circumstances must provide coverage of the drug for the duration of the exigency.

d. § 483.3(u) - IMD Payments

We do not support HHS's proposal to allow states to pay capitation payments to plans for months in which enrollees have a short stay in an IMD. While in theory this practice should provide an incentive for plans to provide necessary crisis services, we believe that it is more likely to have adverse consequences for enrollees who need crisis services and those with high service needs in the community.

There are two main problems with this provision. First, the wording of the proposed regulation would actually allow a stay for much longer than 15 days for the individual. In addition, given that IMDs serve patients with high – and expensive – needs, this provision could create an incentive to require enrollees to use IMDs more often or for longer periods of time because the plan would be receiving the monthly capitation payment when the enrollee was institutionalized. We understand there is variability among states as to whether managed care plans are responsible for payment for IMD services and for how long. Unless the managed care entity is responsible for payment of services to the IMD, this rule creates a significant financial incentive to repeatedly institutionalize individuals with disabilities who could and should be served in the community. Such cycling is often detrimental to long-term successful community placement because it disrupts individuals' services and makes it difficult for them to maintain providers. At the very least, this provision should be changed such that at no point is the managed care entity paid for any month in which an enrollee has stayed in an IMD for more than a 15-day period.

We are also concerned about the selection of the 15-day period, which could amount to up to 30 days over a two day period. The report cited in the preamble as the basis for the selection of the 15-day period specifically states that the demonstration upon which the selection is based did not provide information about IMD services under managed care plans. Also, although the average is cited, there is no further information about the distribution of data to make it clear that an average is actually a reasonable standard that would achieve the purpose of this section. More concerning is that the demonstration did not address inpatient treatment for substance-related disorders.[15] The preamble suggests that this change regarding IMD services would help those with substance use disorders, but there is no information to suggest that the 15-day period would be helpful for this population. Access to inpatient substance use disorder treatment is a significant problem, but it is not clear that this change regarding IMD services would actually provide the appropriate services.

[15] CMS INNOVATION CENTER, REPORT TO CONGRESS ON THE EVALUATION OF THE MEDICAID EMERGENCY PSYCHIATRIC DEMONSTRATION 14 (2013), *available at* http://innovation.cms.gov/Files/reports/MEPD_RTC.pdf.

We strongly recommend that HHS not adopt this rule. However, if it decides to do so, we urge HHS to engage in further research and analysis as to an appropriate time period that would address the needs of people with mental health issues, as well as those seeking substance use disorder treatment.

We also oppose this provision because allowing managed care entities to rely on IMDs for crisis services while continuing to collect payment would set back the current movement toward the development of community-based crisis services. With pressure from the courts and from HHS, states have been moving away from institutional services towards community-based services. In fact, the historical use of "in lieu of services" has been for community-based services. While there is a need for short-term crisis services, the IMD exclusion and thus the exclusion for payments to managed care entities, has provided an incentive for states and managed care plans to only use IMDs on as limited a basis as possible. The trend has been to develop smaller facilities that do not qualify as IMDs due to their size and are often more community-based with fewer institutional characteristics. Such facilities may include community hospitals or specialized crisis centers. They are often more patient-centered, and because they are likely to be more spread throughout the state, usually allow an individual to keep closer ties to the community, family, supports, etc. The preamble recognizes that such services have been effective. To allow provision of payments to managed care entities would sharply decrease the incentive that managed care entities currently have to develop and use such facilities for enrollees.

In addition, there is no protection that enrollees will have the choice they should have for "in lieu of" service. We are very concerned that contrary to long-standing policy regarding "in lieu of" services, enrollees will be forced to select "in lieu of" IMD services as opposed to in a setting covered under the state plan, such as community-based crisis services, because the express purpose of this exclusion is to help with the lack of access to services. A choice between no services or a long wait for community-based services or IMD services is not an unforced choice.

In addition, this provision creates a disparity between those who are under managed care and those who are in FFS. In our experience, there are already many problems for individuals in managed care who become institutionalized, even for a short period of time. For example, the managed care entity may try to disavow responsibility for the individual, refuse to actively participate in discharge planning, and may not fulfill its duties regarding that individual and his or her right to live in the most integrated setting appropriate to his or her needs. This proposal would likely exacerbate this problem or at the very least create longer stays for individuals who would otherwise have shorter stays in such a facility.

While we appreciate the attempt to solve a problem that often occurs for individuals enrolled in managed care, the answer is not to make it easier for individuals to be served in an IMD, but to incentivize the provision of community-based crisis services and appropriate levels of community-based services. The Medicaid program currently

offers numerous opportunities to expand the provision of community-based mental health and substance use services. It does not fit with HHS's stated goal of modernizing these regulations to create a new incentive for Medicaid programs to rely on IMD services.

If this provision is maintained, we request that the following changes be made to ensure that managed care entities are financially responsible for the IMD services to be eligible to receive the capitated payment. Without such a requirement, a managed care entity is rewarded for failing to provide sufficient community resources, including not having a community-based crisis option available and entities will be incentivized to offer an IMD as a crisis placement as opposed to other options. We also recommend that an MCO or PIHP not be eligible to receive a capitated payment if an enrollee has been cycling in and out of an IMD, as discussed previously. A managed care entity should not be rewarded for not repeatedly failing to provide sufficient community services to support an individual such that the person needs repeated crisis services. We also recommend that it be clear that as an "in lieu of" service, to receive the capitated payment the managed care entity must have provided the enrollee meaningful choice between the IMD service and a community-based crisis service.

Therefore, as an alternative to our preferred recommendation that this exclusion not be included in the final regulations, we recommend the following changes:

RECOMMENDATION (ALTERNATIVE TO REMOVAL OF SUBSECTION (u)):

> (u) *Payments to MCOs and PIHPs for enrollees that are* ~~***a***~~ *patient**s*** *in an institution for mental disease**s**.* The State may make a monthly capitation payment to an MCO or PIHP for an enrollee receiving inpatient treatment in an Institution for Mental Diseases, as defined in § 435.1010 of this chapter, so long as:
>
> ***(1) The MCO or PIHP is financially liable for the cost of such inpatient treatment;***
>
> ***(2)*** The facility is an inpatient hospital facility or a sub-acute facility providing crisis residential services, ~~**and**~~
>
> ***(3)*** Length of stay in the IMD is for a short term stay of no more than 15 days during the period of the monthly capitation payment;
>
> ***(4) The MCO or PIHP offered the enrollee the choice of a community-based services or IMD services; and***
>
> ***(4) Within the previous three months, the MCO or PIHP has not received a capitation payment for the enrollee while the enrollee was receiving inpatient treatment in an Institution for Mental Diseases.***

§ 438.4 - Actuarial soundness

We generally support this provision and strongly agree that capitation rates for MCOs, PIHPs, and PAHPs should 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 concur with the Center for Budget and Policy Priorities (CBPP) in supporting the prohibition on creating different in capitation rates based on the FMAP associated with the populations covered. We also support the requirement in (b)(8) that a medical loss ratio (MLR) of at least 85 % be assumed in the capitation rate. We concur with CBPP's recommendation that HHS specify an appropriate upper limit on the medical loss ratios assumed into capitation rates.

We welcome the specification that, in order to be actuarially sound, rates must be adequate to meet the requirements in §§ 438.206, 438.207, and 438.208. We believe, however, that more detail must be provided in order to ensure that reimbursement to providers in Medicaid managed care systems be adequate to ensure sufficient provider participation. HHS has long required that Medicaid managed care rates be actuarially sound.[16] For years, the Medicaid statute and regulations have required MCOs and PHPs to document that they offer a sufficient number, mix, and geographic distribution of providers to meet the needs of the enrollees.[17] Presumably, when they have been setting actuarially sound rates they have been complying with this provision. Yet, NHeLP has worked in a number of states using managed care to deliver services where there are problems with provider participation—resulting in delayed, denied, and more expensive service delivery. We have previously urged HHS to clarify that MCO and PHP rates must comply with the "equal access" standards set in § 1396a(a)(30)(A).[18] We reiterate that recommendation here. HHS is aware that low rates have been a problem in Medicaid, including Medicaid managed care, for decades However, in the recent Supreme Court case *Armstrong v. Exceptional Child Center*, the federal government took the position that providers' ability to bring suits to enforce (30)(A) should be strictly limited because HHS can enforce compliance with the rate provision itself. These regulations present the necessary opportunity for HHS to do just that by issuing regulations that will broadly ensure that the rates that are actually paid to Medicaid-participating providers are sufficient. This will also help ensure that the obligations under proposed § 438.210(a)(2) will actually be met. While the proposed amendments to the actuarial soundness regulations may eventually produce rates that ensure sufficient provider participation, the (30)(A) protection must at least be explicit until that occurs.

RECOMMENDATION: Amend § 438.4(b)(3) by adding the following language at the end of the existing text:

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[16] 42 C.F.R. § 438.6(c)(2).
[17] 42 U.S.C. § 1396u-2(b)(5)(B) (MCOs); 42 C.F.R. § 438.207 (MCOs and PHPs).
[18] *See* Letter from National Health Law Program to Centers for Medicare & Medicaid Services, *Comments on Methods for Assuring Access to Covered Medicaid Services (76 Fed. Reg. 26, 342)* (June 17, 2011).

(3). . . and to ensure that the provider reimbursement rates that MCOs, PIHPs and PAHPs pay to providers are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

§ 438.5 - Rate development standards

We generally support HHS decision to outline the steps that states must follow in setting actuarially sound capitation rates.

We concur with CBPP's recommendation, however, that the final rule clarify what it means to take into account the past medical loss ratios (MLRs) of MCOs, PIHPs, and PAHPs. Specifically, HHS should require that rates include an adjustment to better achieve an assumed MLR of 85 % (or such higher minimum rate determined by States) in order to be actuarially sound. For example, if the actual average MLRs in the prior year were below 85 % (or the higher minimum rate), an adjustment should be incorporated into the rate to take that into account.

§ 438.6 - Special contract provisions related to payment

We concur with CBPP and 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.

We share CBPP's concern 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 reimbursement 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.

We support allowing states to require MCOs, PIHPs and PAHPs to implement value-based purchasing models for provider reimbursement, multi-payer delivery system reform or performance improvement initiatives, and adopt a minimum fee schedule or provide a uniform dollar or percentage increase for all providers. This would help ensure adoption of promising delivery system reforms that can improve care for enrollees while lowering costs and ensure that payment rates are sufficient to ensure adequate access to providers and robust provider participation. We believe, however,

that it is crucial that HHS requiring states to obtain written approval prior to implementation of such requirements and that they demonstrate that the arrangement meets various requirements included in this provision.

We have some concerns about subsection (2). We believe that it needs to have stronger and more specific requirements to ensure that any initiatives conducted under this subsection are conducted in a transparent and in a way that promotes quality and suggest language to this end.

Moreover, on p. 31124, HHS refers to the requirement in subsection (c)(2)(i)(A) that states demonstrated that delivery system and provider payment initiatives be "based on utilization and the delivery of *high quality* services . . ." (emphasis added). That services be high quality is an important requirement. Yet, the regulation itself refers only to "delivery of services." This appears to be an oversight, however, regardless of whether the wording of the regulation was intentional, we urge HHS to amend it.

RECOMMENDATION: Amend subsection (c)(2) as follows:

> (2) *Process for approval.* (i) All contract arrangements that direct the MCO's, PIHP's or PAHP's expenditures must have written approval prior to implementation. To obtain written approval, a state must demonstrate, in writing, that the arrangement—
>
> (A) Is based on the utilization and delivery of ***high quality*** services;
>
> (B) Directs expenditures equally, and using the same terms of performance, for all public and private providers providing the service under the contract;
>
> (C) Expects to ***significantly*** advance at least one of the goals and objectives in the comprehensive quality strategy in § 438.340;
>
> (D) Has a~~n~~ ***comprehensive*** evaluation plan that measures the degree to which the arrangement advances at least one of the goals and objectives in the comprehensive quality strategy in § 438.340;
>
> (E) Does not condition provider participation on intergovernmental transfer agreements; and
>
> (F) ***Is*** ~~N~~***n***ot to be renewed automatically.
>
> (ii) Any contract arrangements that direct the MCO's, PIHP's or PAHP's expenditures under paragraphs (c)(1)(i) or (c)(1)(ii) must also demonstrate, in writing, that the arrangement— . . .
>
> (B) Must use a common set of performance measures across all of the payers and providers ***that are reasonably expected to provide a sufficiently broad and meaningful evaluation of the initiative being implemented***

§ 438.7 - Rate certification submission

We strongly support requiring States to submit to CMS 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 CMS clarify in the final rule that all such information should be publicly available to ensure transparency and public accountability.

We strongly support the requirement that States provide CMS 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 CMS 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 paragraph (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.

In addition, we urge CMS to require explicitly that this information be available to the public. Members of the public should not have to search for this information or make public records requests. Transparency and accuracy of rates are best served when consumers, plans, states, and HHS all have access to all rate certifications and risk adjustment data and assumptions.

RECOMMENDATION: Add a new subsection (e) as follows:

> ***(e) The State must make the information required by this subsection publicly available by posting on the Web site that the State maintains pursuant to § 438.10(c)(3).***

§ 438.8 - Medical Loss Ratio

a. General comments

NHeLP commends HHS for proposing to implement medical loss ratio (MLR) calculation and reporting requirements for Medicaid managed care plans and a requirement for states to use MLRs to set actuarially sound payment rates. Such a policy may help promote consistency in insurance regulation. However, the most important benefit of the policy is that it also promotes transparency and accountability with public dollars. MLRs will allow all governments, industry, and consumers alike to evaluate whether or not Medicaid programs are buying value for enrollees. In addition, we believe the proposed MLR policy will help increase rates for managed care plans that are providing value and reduce payments to plans that are not.

We agree that HHS has the legal authority to implement these MLR provisions, consistent with its statutory obligations under Social Security Act §§ 1902(a)(4) and 1903(m)(2) to efficiently administer the program and pay managed care plans actuarially sound rates, respectively. We agree that a MLR would be a vital tool to further compliance with these statutory mandates.

More specifically, we support three basic features of this rule: (1) the requirement for plans to calculate and report MLR; (2) the requirements for consistent standards for calculating and reporting MLR; and (3) the requirement for states to use the MLRs and MLR history for assessing actuarial soundness and setting payment rates.
NHeLP supports HHS's decision to set a uniform minimum MLR of 85% for states *choosing* to impose an MLR requirement. However (as discussed below), we believe the 85% MLR minimum should be mandatory for plans in all states and enforced through remittance. We are supportive of the additional provisions confirming that states can set a higher minimum limit.

Whether the minimum is enforced through remittance (as we recommend below) or used for rate-setting and actuarial soundness, we believe that 85% is the appropriate number. Data from the Kaiser Family Foundation shows that 28 out of 36 states (78%) for which data was available had average Medicaid managed care MLRs at 85% or higher.[19] As HHS has noted in the preamble to the regulation, the average Medicaid managed care MLR from 2011 to 2013 was 87%.[20] These data indicate that 85% is an appropriate standard that will push for improvement of the lowest performing plans

[19] JULIA PARADISE, KAISER FAMILY FOUNDATION, KEY FINDINGS ON MEDICAID MANAGED CARE: HIGHLIGHTS FROM THE MEDICAID MANAGED CARE MARKET TRACKER 8 (2014), *available at* http://files.kff.org/attachment/key-findings-on-medicaid-managed-care-highlights-from-the-medicaid-managed-care-market-tracker-report.
[20] 80 Fed. Reg. at 31238.

without disrupting the large majority of plans. As HHS has noted, this standard would also bring Medicaid managed care into closer alignment with the private market and Medicare Advantage.

b. Mandatory MLR and remittance

We urge HHS to require states to implement mandatory MLRs of 85% using remittances, as this is the best way to ensure that plans are providing value with certainty and consistency. Such a policy would also better align Medicaid managed care plans with QHPs and Medicare Advantage plans. Medicare Advantage plans have a remittance requirement, along with penalties if they fail to meet the MLR requirement for three consecutive years (disallowed from enrolling new members) and five consecutive years (plan contract termination). We believe the Medicare Advantage policy should be adopted in Medicaid.

We are aware of no evidence demonstrating that mandatory MLRs with remittances would impact Medicaid managed care plans any differently than Marketplace or Medicare Advantage plans.

If HHS is concerned about differential impacts of MLRs on a subset of Medicaid plans, such as safety net plans that may have more fluctuating costs, we recommend that HHS collect data to make an assessment as to whether there is any disproportionate impact.[21] HHS might evaluate data to identify if safety-net plans have more annual MLR fluctuation in costs because: (1) they shore up certain regions by continuing coverage when the area becomes unprofitable (while other plans leave the area); or (2) they carry a higher risk population (e.g., more dual eligibles). Such fluctuations might mean a plan regularly sees a spike in services costs (and MLR) in one year and needs a lower MLR in a subsequent year to "break even." Such plans would be harmed by remittance because they would be forced to remit on every "break even" year, even if there MLR was above the 85% threshold on average. To the extent that HHS has concerns about the negative differential impacts of an MLR and remittance policy in Medicaid, our recommendation is that HHS collect specific data to identify whether there are any verifiable concerns for safety-net health plans, and if there are, develop an adjusted MLR and remittance policy for those plans.

Specifically, the policy for such plans might apply the 85% minimum MLR requirement on a rolling 3 year average to "smooth out the data." We believe that even for safety-net plans, such a policy would be preferable to only using MLR in the actuarial soundness and rate-setting processes. For example, if HHS data confirms that it is true that safety-net plans have wider fluctuations in their MLR values (for example, 84%, 92%, 82%, over three consecutive years, for an average of 86%) as compared to other plans (for example, 86%, 87%, 85%, over the same three years, for the same average), HHS

[21] HHS might identify or define safety-net health plans by reliance on criteria similar to those found in ACA § 9010(c)(2)(C).

could consider applying 3 year averages to safety net plans to level the playing field. Ultimately, such an exception should *only* be implemented if there is solid evidence demonstrating that a subset of Medicaid plans providing unique value is differentially harmed by a MLR and remittance policy.

c. § 438.8(e)(3) - Activities that improve health care quality

We commend HHS for including care coordination, case management, community integration activities, and other important services in the MLR numerator. While we know that it will be challenging for HHS and states to distinguish genuine health care quality activities from administrative expenditures that may only be peripherally related to conducting health care quality activities, we agree that it is critical for HHS to ensure that there is no disincentive to conduct care coordination and related activities. HHS' proposed regulation relies on Marketplace regulation 45 C.F.R § 158.150 to define activities that improve health care quality. We believe HHS should re-evaluate that definition to ensure that no part of it could be used to block inclusion in the MLR numerator of care coordination, case management, community integration, or other services that improve the health of enrollees. We recommend that, to be safe, HHS should use more explicit language in the regulation to assure inclusion of the most important activities, or failing that, issue subregulatory guidance to this effect. HHS must also evaluate if any essential "non-medical" quality activities might go unrecognized under the regulatory standards of § 438.8(e)(3) (and 45 C.F.R. §§ 158.150(b) and (c)), such as language services and non-emergency medical transportation. HHS should clarify that non-emergency medical transportation should be counted in the MLR numerator (whether as an incurred claim or activity improving health care quality) regardless of whether it is technically claimed as an administrative or service cost by the state, to ensure states do not have a disincentive to provide the services. Ultimately, we believe that more explicit standards will also help HHS draw the line between true health care quality activities and loosely-related administrative activities.

It is our belief that, historically, plan MLR calculations in the private market have been padded with administrative activities, and states have done a weak job enforcing the integrity of the MLR standard. Therefore, we also recommend that HHS take a proactive approach in monitoring the content of health care quality activities. HHS should prescribe how states should approve and audit plan calculations, and HHS should itself audit state criteria or data for a diverse sample of states every two years.

RECOMMENDATION: Amend § 438.8(e)(3)(i) as follows:

> (i) An MCO, PIHP, or PAHP activity that meets the requirements of 45 CFR 158.150(b) and is not excluded under 45 CFR 158.150(c)***, including all care coordination, case management, activities that support community integration, language access, and non-emergency medical transportation services***.

d. § 438.8(e)(4) - Fraud and abuse

We understand HHS's desire to support prevention of fraud and abuse, and we agree that this is a priority for the Medicaid program. However, we do not agree that this priority should be advanced through the MLR calculation. Plans are supposed to select their providers carefully and they are expected to not engage in fraud and abuse. To the extent that any providers (or plans) have historically engaged in such activities, that is an administrative failure on the part of the plans, and correcting it is a "cost of doing business" that should not detract from the value that state and federal governments receive for public health care dollars they spend. There are numerous other channels of enforcement and monitoring that are far more appropriate and effective for preventing fraud and abuse than the MLR calculation. We do not believe such administrative expenses should be included in the numerator (or deducted from the denominator). We also note that it would be administratively challenging, if not impossible, to distinguish administrative activities related to fraud prevention (for example, a review of outlier claims for fraud review purposes) from: (1) those same activities conducted for other purposes (for example, for administrative efforts to identify cost-saving opportunities); and (2) administrative activities that indirectly relate to fraud prevention (for example, the collection of routine data that happens to be used in a subsequent outlier claims review). For these reasons we recommend that HHS delete the provision to include fraud and abuse spending in the MLR numerator at § 438.8(e)(4).

e. § 438.8(f)(2)(iv) - Unpaid cost-sharing

We strongly oppose the inclusion of unpaid cost-sharing amounts in the premium revenue component of the MLR denominator and thus recommend that HHS delete § 438.8(f)(2)(iv). Plans already have a financial incentive to collect these revenues and HHS does not need to increase that incentive further through the MLR calculation. The purpose of an MLR is to ensure that revenues are spent on necessary services. However, multiple studies have demonstrated that cost- sharing discourages beneficiaries from using services that they need. It is therefore inappropriate to formulate the MLR in a way that incentivizes plans to collect cost-sharing. It also is unclear how HHS' proposed policy would account for the fact that Medicaid cost-sharing is not generally enforceable for populations below 100 % FPL.

We also note that the FFS fee schedules that are often the base figure for developing capitation (and subcapitation) rates do not generally include cost-sharing, so it would not be consistent to blend them into capitation rates.

f. § 438.8(f)(3)(v) - Community benefit expenditures

While we support plan community benefit expenditures, we do not believe they should be excluded from the MLR denominator as proposed in § 438.8(f)(3)(v), unless they are *required* to meet the plan's non-profit or tax-exempt status. Charitable discretionary spending by a plan should not inflate the MLR potentially at the expense of contractually

mandated service delivery. To the extent that HHS decides to count such spending, we believe it should be limited to 1% of the premium.

g. Subcontracting

We recommend that HHS modify the regulation to require that the MLR requirements applying to an 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, they could all count in the numerator (incurred claims), however, if a contractor only performs administrative functions, they 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.

h. Technical issues

We believe there may be three technical errors in the proposed regulation and preamble:

- Proposed § 438.5(b)(5) refers to "§ 438.4(b)(7)" when the intended cite may be § 438.4(b)(8).
- This same error may be repeated in the regulation preamble at 80 Fed. Reg. 31109.
- This same error may be repeated in the regulation preamble at 80 Fed. Reg. 31171.

§ 438.9 - NEMT PAHPs

We commend HHS for proposing to expand regulation of PAHPs. However, we are concerned with HHS' decision to exclude NEMT PAHPs from much of this regulation. With respect to the majority of the provisions in part 438, NEMT PAHPs are no different than other PAHPs that only provide a single service, such as dental PAHPs. In fact, capitated NEMT PAHPs have the same financial incentives as other PAHPs to limit enrollees' access to services. As a result, we believe that the regulations that apply to PAHPs and to states that contract with them should apply to NEMT PAHPs unless, due to the nature of the services that NEMT PAHPs provide, they simply cannot apply or are wholly unnecessary. With this standard in mind, HHS should amend § 438.9 to include most of the regulations in part 438 that apply to PAHPs and to states that contract with them.

For example, § 438.9 would exempt NEMT PAHPs from the requirement to have a grievance system in place. HHS states that a grievance system "does not seem appropriate" for NEMT PAHPs because "[t]he reasons for requiring PAHPs that cover medical services to adhere to the grievance and appeals processes in this subpart are not present for a PAHP solely responsible for NEMT."[22] We disagree. HHS points to the fact that PAHPs that cover medical services may use medical management techniques as the reason for requiring these PAHPs to establish a grievance system.[23] While NEMT PAHPs do not use traditional medical management techniques, they do decide when Medicaid beneficiaries receive requested transportation services and when they do not.[24] And, as noted above, NEMT PAHPs have the same financial incentives as other PAHPs to limit enrollees' access to covered services. Thus, enrollees in NEMT PAHPs should have the same right as enrollees in other PAHPs to file an internal appeal to challenge a denial of services. Moreover, like enrollees in other PAHPs, enrollees in NEMT PAHPs should have the ability to register a complaint with the PAHP about the quality of services received. The quality of NEMT services has been and continues to be a significant problem for Medicaid beneficiaries in many states, with beneficiaries reporting that transportation providers frequently arrive late or not at all. While we recognize that the requirement to establish a grievance system does impose an administrative burden on PAHPs, we see no compelling reason to distinguish NEMT PAHPs from other PAHPs that only provide a single service with respect to this requirement.

RECOMMENDATION: At a minimum, HHS should apply the following additional regulations to NEMT PAHPs and to states that contract with them: §§ 438.8, 438.52, 438.54, 438.62, 438.66, 438.70 – 438.74, 438.206 – 438.208, 438.228, subpart E, subpart F, subpart H, and §§ 438.810 – 438.818.

In addition, we are concerned that states, beneficiaries, and other stakeholders might not understand when a given NEMT entity is a broker (established under 42 U.S.C. § 1396a(a)(70)) and/or a PAHP, and thus, which regulations apply with respect to the entity. In order to ensure that states, brokers, and PAHPs understand their obligations, and that beneficiaries understand their rights, we ask HHS to issue guidance explaining the distinction between NEMT brokers and NEMT PAHPs. Such guidance will promote transparency in state Medicaid programs.

[22] 80 Fed. Reg. 31098, 31103.
[23] *Id*.
[24] We want to note here the importance of ensuring that states and managed care entities understand the requirement to provide transportation services to and from covered abortion services when necessary. This is particularly critical in states where, due to state law restrictions on abortion providers, individuals must travel long distances to access covered abortion services.

§ 438.10 - Information requirements

Access for people with disabilities or Limited English Proficiency (LEP) is critical to ensuring that a state's Medicaid program provides appropriate services to all participants, including managed care enrollees. Disability- and language-related barriers to access may severely limit an individual's opportunity to access medical care, assess options, express choices, and ask questions or seek assistance. Culturally and linguistically appropriate services and assistance are necessary for individuals to access Medicaid services and providers. Managed care plans especially need to protect and promote access because they often have limitations, such as more limited networks of providers, which may lead to access problems and limited care.

a. § 438.10(a) - Definitions

We are concerned about the definition of "prevalent" in terms of setting standards for language access and the reference to standards "used by the Office for Civil Rights (OCR) in enforcing anti-discrimination provisions." We are unsure what standards the proposed regulation refers to as the only public standards are outlined in OCR's "LEP Guidance" (LEP Policy Guidance for HHS Recipients, August 8, 2003). If the regulation intends use of the standards in the LEP Guidance, we believe it should specifically include those standards. If HHS intends other standards, it would be difficult for any covered entity or advocate seeking to enforce the regulation to know how to comply since these standards are not specifically outlined and may be internal standards used by OCR that are not public. We do not believe any internal standards should form the basis for determining how to provide language services.

All entities covered under this proposed rule receive federal funds and thus must comply with both Title VI and § 1557 of the Affordable Care Act (ACA). We believe this requirement should be explicitly stated in the regulation. Title VI (42 U.S.C. § 2000d *et seq*.) prohibits discrimination by any entity receiving Federal financial assistance. In addition, § 1557 of the ACA prohibits discrimination in any "health program or activity, any part of which is receiving Federal financial assistance," which includes every MCO, PIHP, PAHP and PCCM. Thus, every one of these entities is obligated under both Title VI and § 1557 not to discriminate, and that means that they must provide culturally and linguistically appropriate services. OCR's longstanding guidance has outlined standards for compliance pursuant to Title VI. We do not believe HHS should now change the standards and instead utilize a "prevalent" language standard that may or may not be public.

It is well documented that language barriers affect access to health care. The Institute of Medicine has stated that:

> Language barriers may affect the delivery of adequate care through poor exchange of information, loss of important cultural information, misunderstanding of physician instruction, poor shared decision-making,

> or ethical compromises (e.g., difficulty obtaining informed consent). Linguistic difficulties may also result in decreased adherence with medication regimes, poor appointment attendance, and decreased satisfaction with services.[25]

As recognized throughout the proposed rule, it is critical that consumers have access to vital information about their insurance plan in a language in which they are conversant. Thus we strongly believe that the standards for entities covered by this proposed rule should not now be weakened to an unknown and unspecific standard.

HHS's LEP Guidance built upon Executive Order 13166, which required federal agencies to publish guidance describing how their recipients can provide meaningful access to LEP persons.[26] In that Guidance, HHS recognized that "[t]he more frequent the contact with a particular language group, the more likely that enhanced language services in that language are needed."[27] The Guidance provided two "safe harbors" or rules that recipients of federal funds could follow and be sure they were in compliance with Title VI: first, the HHS recipient provides written translation of vital documents for each eligible LEP language group that constitutes 5% or 1,000, whichever is less, of the population of persons eligible to be served; and second, if there are fewer than 50 people in a language group that reaches the 5% threshold, the recipient can provide written notice of the right to receive competent oral interpretation of the written materials, free of cost. These criteria have been practicable for all recipients of Federal financial assistance – which included the entities already participating in Medicaid – for more than twelve years. Accordingly, we recommend that they be specifically incorporated into this regulation.

LEP Guidance from the Department of Justice (DOJ) and HHS (see http://www.lep.gov/guidance/guidance_index.html) recognize the need for a dual standard for translating documents and include both numeric and percentage thresholds. Depending on the size and composition of a covered entity, one might be more applicable than the other, and merely having a numeric threshold or a percentage – and not both – would weaken current LEP standards. We thus recommend that HHS adopt the OCR Guidance safe-harbor standards of 1,000 or 5% of a plan's potential enrollees or enrollees, whichever is less. The 5% is also used in regulations from the Centers for Medicare & Medicaid Services governing marketing by Medicare Part C & D plans.

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[25] INST. OF MED., UNEQUAL TREATMENT: CONFRONTING RACIAL AND ETHNIC DISPARITIES IN HEALTH 17 (2002)(citations omitted).
[26] "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons," 68 Fed. Reg. 47311 (August 8, 2003). This Executive Order was reaffirmed on June 28, 2010 and again on February 17, 2011.
[27] 68 Fed. Reg. 47314.

As some plans may undertake specific marketing and outreach activities to particular ethnic/cultural/language groups, we also recommend that HHS adopt a secondary requirement to provide language services to any language group to which the plan specifically markets. This must be *in addition to* the basic thresholds. This standard would recognize that a plan could not conduct marketing and outreach to enroll LEP members and then fail to provide assistance when those members need additional information.

Finally, we strongly believe that ***regardless of whether a plan is required to provide written translations*** of materials, HHS must ensure that oral assistance – through competent interpreters or bilingual staff – is provided to ***all*** LEP enrollees.

In sum, entities covered by this proposed rule have known the relevant standards for providing services to LEP individuals since 2003, and these same standards should form the basis for explicit standards in this rule, rather than a delegation to "prevalent" languages. To require anything less than the same language access that is required of other recipients of Federal financial assistance would undermine the intent of the ACA's requirement of linguistic and cultural appropriateness, as well as Title VI and § 1557's promise of nondiscrimination. The rule should be amended to bring it into compliance with the HHS Guidance, at the very least.

We also recommend that HHS specifically include requirements that the standards for determining prevalent languages must be done on the basis of the entity's service area and not a county or state. Different entities will have different service areas and it is not sufficient to use county or state data that may be under- (or in some circumstances over-) inclusive. For example, an MCO's service area may span many counties within a state, but a particular PIHP or PAHP may only serve a smaller area, and requirements to provide translations should depend on the most relevant service area for each entity.

RECOMMENDATION: Amend subsection § 438.10(a)'s definition of "prevalent" as follows:

> *Prevalent* means a non-English language determined to be spoken by ~~a significant number or percentage of~~ ***1,000 or 5% 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.***

b. § 438.10(b) - Applicability

We support the changes made to subsection (b) including HHS's recommendation to have this section apply across all managed care entities (MCOs, PAHPs, PIHPs, PCCM entities, PCCMs) and types of managed care (state plan and waiver).

c. § 438.10(c) - Basic rules

We commend HHS for recognizing the importance of transparency in improving access to, and quality of, Medicaid managed care services. In 2010, NHeLP joined with state advocates as part of our Medicaid Managed Care Sunshine and Accountability Project ("Sunshine Project"). We encountered significant resistance from Medicaid managed care companies that refused to provide information on managed care operations and services. In addition, some state agencies did not have the information in a readily accessible, understandable format.

During the Sunshine Project and since, NHeLP, other health advocates, and legal aid attorneys have often been compelled to file public records requests to obtain information because the managed care regulations do not expressly require that the information be made publicly available. Therefore, we strongly support replacing the current regulation with more a coherent and structured framework for making information available to enrollees, potential enrollees, advocates, and other stakeholders.

The proposed regulation at § 438.10(c)(3) greatly expands transparency by requiring states to post to the state Medicaid agency website: the enrollee handbook, provider directory, state network adequacy standards, EQR technical report, contracts, audits, and encounter data. We strongly support this provision and think it should be broadened.

As proposed, the regulation distinguishes between certain types of information that must be provided to potential enrollees (e.g., individuals determined Medicaid-eligible by the state but who have not yet selected a managed care plan, § 438.10(e)); and enrollees (individuals enrolled in a plan, § 438.10(f)).

We agree that certain types of information can be useful to potential enrollees to aid in selecting select a plan, such as general information on managed care, providers, services, cost sharing (if any); while other information may be more useful to persons who are already enrolled, such as information on the right to disenroll, terminated providers, and physician incentive plans.

However, the distinction between potential enrollees, enrollees, and the public should be a matter of targeting information, rather than who may obtain information. Information may also be useful to individuals other than enrollees and potential enrollees. For example, case managers, care coordinators, consumer assisters, legal services providers, and advocates may need to obtain information on terminated

providers, which under the proposed regulation must be provided only to current Medicaid enrollees.

Accordingly, we recommend that HHS strengthen and broaden the Medicaid managed care transparency and public reporting provisions by requiring that states make all information provided to enrollees and potential enrollees publicly available.

Final regulations should also require public reporting of disenrollments (whether by the member or the health plan), and the reasons for those disenrollments, which will provide a basis for comparison shopping for consumers and inform the State agency about the performance of the plans with which it is contracting,. Similarly, final regulations should require public reporting regarding of plans' statistics of denials and partial denials of health services (i.e., where the plan did not provided the full amount of health services requested by the provider). It is possible that some of this information will be captured in monitoring reports or EQRs if those sections are modified as suggested in these comments but such reporting should be independent transparency requirements under the final regulations.

RECOMMENDATION: Amend § 438.10(c)(3) as follows:

> (3) The State must operate a Web site that provides ***to the general public*** the content specified in paragraphs ***(e) through*** ~~(g) and~~ (h) of this section, § 438.68(e), **§ 438.74, § 438.242;** § 438.364(b)(2), and § 438.602(g), either directly or by linking to individual MCO, PIHP, PAHP or PCCM entity Web sites.
> (4) **The State must publish on its Web site statistics on (a) disenrollments, whether initiated by the health plan or the member, and the reasons for said disenrollments and (b) denials and partial denials of health services. A partial denial occurs where the MCO, PIHP, PAHP or PCCM provides less than the full amount of service requested by the provider.**

We also have a question about subsection (c)(7), as we are unclear what the intended mechanism might be to help enrollees and potential enrollees. If this is intended to be the beneficiary support system as outlined in § 438.71, then we would suggest including a specific cross-reference to that section. If it is not this system, then we would request HHS add further clarification as to what type(s) of mechanisms are envisioned and permitted.

d. § 438.10(d) - Language and format

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

First, in subsection (1), we are concerned that the methodology to determine "prevalent" languages is left up to the state. As we commented with regard to subsection (a) and

the definition of "prevalent," we believe the standards are well established for determining into what languages the state and managed care entities should translate documents. Leaving the determination up to the state would undermine the longstanding OCR LEP Guidance as well as likely result in a patchwork of standards that create different results in different states, putting LEP enrollees and potential enrollees at the mercy of their state to determine whether they will receive in-language materials. Rather, as OCR has set national standards for translation in the LEP Guidance, we strongly believe HHS should adopt these standards for Medicaid to determine prevalent languages and not allow 50 different variations. This is particularly critical due to the fact that forty-plus years after adoption of Title VI of the Civil Rights Act of 1964, many LEP individuals still suffer discrimination and do not receive the language assistance to which they are entitled. If a state wants to implement stricter standards, HHS should allow it, but the standards from the OCR LEP Guidance should provide the basic minimum requirements to determine prevalent languages.

Second, subsection (2) implies that oral interpretation only has to be provided in prevalent languages. Given other parts of this section (e.g. subsection (5)), we do not believe this is the intent and thus suggest re-wording this subsection to specifically require that oral interpreting must be provided for all enrollees and in all languages, not merely prevalent languages.

Third, we suggest that HHS require a minimum number of taglines be included on notices. For example, under the recent "payment & parameters" final regulation, private insurers must include taglines in at least 15 languages.[28]. While certain materials must be provided in prevalent languages, it is likely that many entities will have LEP enrollees whose language group does not meet the threshold. Since taglines are an easy way to inform individuals about the availability of language services, we do not believe the number of taglines should be related to the number of prevalent languages, but rather that taglines can help inform additional LEP individuals about language services. That is, only requiring taglines in the prevalent languages would only ensure that LEP individuals speaking those languages receive notice about language services when, in fact, these individuals should already be receiving notices in their language. Thus, the purpose of the taglines should be twofold – provide notice to those who speak prevalent languages that they can get in-language written materials, but also inform a wider group of LEP individuals in their languages that oral interpretation is available. We thus suggest including the same requirements for MCOs, PIHPs, PAHPs, PCCM entities, and PCCMs as in the payment & parameters regulation. We also recommend that the regulation require that taglines be prominent and not hidden at the end of long documents, handbooks or notices where they are unlikely to be seen by an LEP individual who may not flip through a multi-page English document.

The Social Security Administration, through its Multilanguage Gateway (http://www.ssa.gov/multilanguage/), translates many of its documents into 15

[28] 45 C.F.R. § 155.205.

languages, and CMS plans to translate Medicare forms, including notices, into 15 languages in addition to Spanish.[29] Already CMS currently provides some vital documents in Arabic, Armenian, Chinese, Farsi, German, Greek, Haitian Creole, Italian, Korean, Polish, Portuguese, Russian, Spanish, Tagalog, and Vietnamese.[30] Further, plans that operate in California are already required to do provide a minimum number of taglines and have adapted to this. For example, Standard Insurance Company sends an insert with all Coverage of Benefits documentation that includes taglines. The tagline used by this insurer states:

> "No Cost Language Services. You can get an interpreter and get documents read to you in your language. For help, call us at the number listed on your ID card or xxx-xxx-xxxx. For more help, call the CA Department of Insurance at xxx-xxx-xxxx."

The Federally Facilitated Marketplace also utilizes taglines on its notices. It recently revised its taglines to emphasize the importance of documents and information that could impact an enrollee's rights and coverage. HHS could share those taglines with states and covered entities to reduce the costs of having to independently translate taglines.

Taglines are an effective and cost-efficient manner of informing LEP individuals and will help assist plans in determining in which languages additional materials should be provided. And to reduce costs to plans, the Departments can provide tagline language and translations for plan usage if plans did not wish to develop their own.

RECOMMENDATION: Amend § 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.
>
> (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. . .

With regard to the "vital" documents delineated in subsection (3), we suggest specifically adding notices related to denials of requests for services (including prior authorizations) and termination notices. To the extent that an enrollee may lose coverage or have a provider-recommended service denied, these enrollees should

[29] *See* CMS, STRATEGIC LANGUAGE ACCESS PLAN (updated 2014), *available at* http://www.cms.gov/About-CMS/Agency-Information/OEOCRInfo/index.html.
[30] *Id*. at 9.

receive in-language notices to appropriately notify them of the right potentially being taken away so they have the necessary information to counter the action.

RECOMMENDATION: Amend § 438.10(d)(3) 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, notices if a provider no longer participates in the plan,*** and other notices that are critical to obtaining services. . ..

In subsection (4), we appreciate the recognition of the need for competent interpreters. We comment below on the need to maintain consistency in terminology (and suggest changing "skilled interpreter" to "competent interpreter" for listing in provider directories). Here, we suggest specifically defining, either in this subsection or the definitions section, what a "competent" interpreter is. Unfortunately, widespread misunderstanding continues about the required knowledge, skills, and abilities needed to be a competent healthcare interpreter, and we do not want to see this subsection diluted in practice. As reference, NHeLP developed, in conjunction with 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.

RECOMMENDATIONS: **1**. Amend § 438.10(d)(4) 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 that the State identifies as prevalent.

2. Add the following definitions to § 438.10(a):

> ***Competent interpretation services mean the provision of interpreting by a competent healthcare interpreter.***
>
> ***A competent healthcare interpreter is an individual who can accurately and faithfully render a message spoken in one language into a second language (the second language can be a non-English language or American Sign Language).***
> ***(i) A competent medical interpreter for a non-English language is either:***

(a) An individual who has been certified by a national certifying body for interpreting in healthcare; 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:
(A) specialized healthcare terms and concepts; and
(B) 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.

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

Competent translation services means the conversion of written text in to a corresponding written text in a non-English language that results in an accurate rendition of the English materials into the non-English language.

A competent healthcare translator is an individual who can accurately and faithfully translate a message written in one language into a second language.
(1) A competent translator is either:
(a) An individual who has been certified in translation by a national translation certification entity;
(b) A qualified translator who demonstrates the following skills:
(1) is over the age of eighteen;
(2) is proficient and able to communicate written 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:
(A) specialized healthcare terms and concepts; and
(B) any particularized vocabulary and phraseology used in the document to be translated, such as regional usages of terms;
(4) possesses exceptional research skills and be able to access reference materials that are essential for producing high-quality translations;
(5) attests to comply with the Code of Professional Conduct and Business Practices of the American Translators Association; and
(6) attests to adhere to HIPAA requirements to the same extent as the healthcare provider for whom interpreting is provided.

In § 438.10(d)(6), we recommend adding a clarification to (ii) that cross-references back to the requirement for a large print tagline. While we recognize that (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) as follows:

(ii) Use a font size no smaller than 12 point, ***except as required in subsection (d)(3)(i).***

e. § 438.10(e) - Information for potential enrollees

We appreciate that MCOs, PIHPs, PAHPs, and PCCM entities must provide potential enrollees with information about Medicaid benefits not covered by the entity, including family planning services and supplies and abortion services not covered by a plan due to religious objections. If potential enrollees know that a particular plan does not cover certain services, and obtaining these services through the plan is important to them, they can choose a plan that does cover the services. We thus suggest amending § 438.10(e)(2)(v) to require entities to provide similar information to potential enrollees.

We also recommend including PCCM entities in this section, as their omission from this part of the regulation seems to be an unintentional change from the current regulations and inconsistent with other parts of the proposed regulation (*see* § 438.10(g)(2)((ii)(A), (B)). To the extent that PCCM entities have to inform enrollees if they do not cover a service (see subsection (g)(2)(ii)(A)-(C)), we believe the state should have an up-front responsibility to inform potential enrollees if PCCM entity does not cover a particular service.

RECOMMENDATION: Amend § 438.10(e)(2)(v) as follows:

(v) Covered benefits, including
(A) Which benefits are provided by the MCO, PIHP, PAHP, ***or PCCM entity, . . .***
(C) For a counseling or referral service that the MCO, PIHP, ~~or~~ PAHP ***or PCCM entity*** does not cover because of moral or religious objections, the State must provide information about where and how to obtain the service. ***The MCO, PIHP, PAHP, or PCCM entity must inform potential enrollees how they can obtain information from the State about how to access those services.***

f. § 438.10(f) - Information for all enrollees of MCOs, PIHPs, PAHPs and PCCM entities: General requirements

We are concerned that notice is only sent about termination of a provider's contract when an enrollee was seen on a "regular" basis by the provider. The regulation does not define "regular," and we believe that even if an enrollee has only seen a provider once, the enrollee still deserves notice of termination. For some providers, "regular" may be only once per year, such as a woman going to see her gynecologist for a yearly well-woman visit. While a woman may only see a particular gynecologist once per year, the enrollee likely would return the following year assuming the provider remained in the network and should receive notice if the provider's contract ends. It is unclear under the proposed rule whether this would this be considered "regular." As another example, some individuals with disabilities may see multiple providers, although none "regularly," as it would depend on whether a particular need arises. Thus, we strongly recommend that HHS instead require managed care plans to notify enrollees of the termination of any provider the enrollee visited. As an alternative, if HHS wants to impose some time limit, we recommend defining "regular" or setting a timeframe of an enrollee receiving care from the provider at least once within the previous twelve months. California already has this requirement in its Knox-Keene Act.

RECOMMENDATION: Amend § 438.10(f) as follows:

(f) *Information for all enrollees of MCOs, PIHPs, PAHPs, and PCCM entities: General Requirements:* (1) The MCO, PIHP, PAHP and, when appropriate, the PCCM entity, must make a good faith effort to give written notice of termination of a contracted provider, within 15 calendar days after receipt or issuance of the termination notice, to each enrollee who received his or her primary care from, or was seen ~~on a regular basis~~ ***at least once in the last twelve months*** by, the terminated provider.

We also recommend that the regulations include a requirement that plans inform enrollees that they can request that communications containing medical information, including services received and providers seen may 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, such as adolescents receiving certain services they do not want their parents knowing about (e.g. family planning services or supplies) and other enrollees seeking "sensitive" services (e.g., victims of intimate partner violence, etc.). All covered entities should be required to honor, and enrollees should be permitted to request, that plan communications are sent to a specific e-mail or mail address or telephone number. In addition, we recommend that the state and covered entities tell the enrollee that they can make this request. Entities should provide notices that explain that enrollees have a right to designate a specific mail or email address or telephone number at which to receive plan communications, which may be different from the address provided by other household members. The notice should clearly explain how to make that request and it should provide a link to forms or a phone number to call.

RECOMMENDATION: Amend § 438.10 (f) to add new subsection (4):

> ***(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, including services received and providers seen, 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.***
>
> *g. § 438.10(g) - Information for enrollees of MCOs, PIHPs, PAHPs and PCCM entities – Enrollee handbook*

In subsection (g)(1), we recommend that HHS include a specific timeframe rather than "a reasonable time after receiving notice of the beneficiary's enrollment." In subsection (c)(6)(v), enrollee information must be provided in paper form within 5 calendar days. We suggest HHS include this same timeframe in subsection (g).

RECOMMENDATION: Amend § 438.10(g)(1) as follows:

> (1) Each MCO, PIHP, PAHP and PCCM entity must provide each enrollee an enrollee handbook within ~~reasonable time~~ ***5 calendar days*** after receiving notice of the beneficiary's enrollment. . .

We appreciate that CMS has consistently confirmed that enrollees are entitled to freedom of choice for family planning. Due to the sensitive nature of family planning services and the prolonged period of time that individuals require them, it is important that each beneficiary have ready access to a family planning provider with whom they are comfortable and who is familiar with their health history. In recognition of these facts, the federal Medicaid Act provides individuals enrolled in Medicaid with the right to choose their family planning providers, so long as those providers are qualified and willing to accept Medicaid payment for their services. Freedom of choice preserves not

only continuity of care, but also confidentiality. Moreover, as noted in the preamble, 42 C.F.R. § 441.20 requires that "each beneficiary is free from coercion or mental pressure and free to choose the method of family planning to be used." Taken together, the freedom of choice provision and the freedom from coercion requirement are intended to ensure that enrollees can obtain all family planning services and supplies and all family planning-related services that are covered by the State plan, regardless of whether a particular service or supply is covered by the MCO, PIHP, PAHP and PCCM entity. To ensure the final rule reflects existing law, we recommend that HHS amend the regulation.

RECOMMENDATION: Amend subsection (g)(2)(vii) as follows:

> (vii) The extent to which, and how, enrollees may obtain benefits~~, including family planning services, and supplies,~~ from out-of-network providers***, including informing enrollees of their right to obtain family planning services and supplies and family planning-related services from any Medicaid provider without limitation or prior authorization.***

In subsection (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 particularly in the case of fair hearings which would be conducted by an entity external to the MCO entity, specific requirements for language services and accommodations for individuals with disabilities should be specified.

RECOMMENDATION: Amend § 438.10(g)(2)(xi) to add new (F) as follows:

> ***(F) 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.***

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

RECOMMENDATION: Amend § 438.10(g)(2)(xiii) as follows:

> (xiii) How to access auxiliary aids and services ***and oral translation and written materials***, including additional information in alternative formats or languages.

We are somewhat confused how the requirements of subsection (g)(3) interact with subsection (c)(6). Subsection (c)(6) outlines when information may be provided electronically. However, subsection (g)(3)(ii) and (iii) do not refer back to (c)(6). We thus suggest that subsection (g) specifically cross-reference (c)(3) so those requirements clearly apply. In addition, on the website where the entity posts the information, we also suggest the entity note information how to request a paper copy as that is an option available under (c)(6).

RECOMMENDATION: Amend § 438.10(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 Web site 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. . .

Further, with regard to subsection (g)(iii), we strongly support the requirement for plans that wish to provide information solely on their 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 subsection (g)(ii).

We also noted a minor technical drafting error. In subsection (g)(2)(ii)(B), the text currently reads "The MCO, PIHP, PAHP, or PCCM entity must inform enrollees how they **can to** obtain information from the State. . ." (emphasis added). We believe inclusion of both "can" and "to" is not needed and suggest deleting "to".

We also suggest adding additional information requirements to the list included in (g). We believe it is important that enrollees understand how to obtain services during a transition, utilization review, and other factors that impact how the managed care entity works.

RECOMMENDATION: Amend § 438.10(g)(2) by adding the following:

> ***(xvii) Information on how to obtain continued services during a transition, as provided in § 438.62.***
> ***(xviii) Information related to external quality review, as set forth in § 438.364(b).***
> ***(xviv) The State's standards for access to care that must be developed pursuant to 42 U.S.C. § 1396u-2(c)(1)(A).***
> ***(xv) Information related to utilization review, including clinical coverage guidelines.***

h. § 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 capabilities. For example, a provider who has only taken high school language classes is very likely not proficient to provide healthcare services in a non-English language. Thus, it is important that if a provider self-identifies as speaking a non-English language and providing services in that language, the provider has sufficient proficiency to do so. Some providers may have some proficiency but are not completely bilingual, particularly when it comes to knowledge of specialized healthcare terminology. They may be able to greet a person who is LEP in his or her language, but may not have sufficient language skills to take a health history or provide healthcare services in that language. The distinction is critical to ensure meaningful communication and appropriate allocation of resources. 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 thus recommend clarifying this provision to require that the provider is sufficiently competent to provide services in a non-English language and not just have basic conversational skills. Thus, we recommend 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 a non-American sign language.

RECOMMENDATION: Amend § 438.10(h)(1)(vii) as follows:

> (vii) 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:***
>
> ***(1) 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***
>
> ***(2) possesses proficiency in the non-English language or sign language for which services will be provided including knowledge of:***
>
> ***(a) specialized healthcare terms and concepts in both languages; and***

(b) 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. We suggest, however, that HHS provide some explanation of what "skilled" means, either in this section or in the definitions section. First, we would recommend changing "skilled" to "competent." To be an effective interpreter, an individual must possess the requisite knowledge, skills and abilities. Skills alone are insufficient. For example, in surveying the healthcare interpreter field to develop its certification examination, the Certification Commission for Healthcare Interpreters (www.cchicertification.org) identified 6 "skills" (including active listening, retaining information in short term memory, note taking) but over 20 "knowledge" domains and 20 "abilities."[31] An individual could meet the skills required to be an interpreter, but not have the knowledge or abilities. As a result, using the term "skilled" interpreter does not sufficiently capture the requirements for an effective interpreter.

Second, 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 does identify 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. Thus, a provider should not be able to note in a provider directory that the provider has interpreters unless the interpreters are truly competent.

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 in the U.S. for interpreters working with individuals who are deaf or hard of hearing.

RECOMMENDATION: In § 438.10(h)(1)(vii), change "skilled" to "competent". If a definition of "competent medical interpreter" is not added to subsection (a), add the following definitions (either in subsection (a) or to clarify subsection (h)(1)(vii):

(A) A competent medical interpreter for a non-English language is either:

[31] *See, e.g.*, CERTIFICATION COMM'N FOR HEALTHCARE INTERPRETERS, JOB TASK ANALYSIS STUDY AND RESULTS, MAY 14, 2010, at 10-11 (2010), *available at* http://www.cchicertification.org/images/webinars/cchi%20jta%20report-public.pdf.

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

(ii) 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:

(a) specialized healthcare terms and concepts; and

(b) 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.

(B) 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 competency 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. “Machine translation” refers to the use of a computer program to automatically translate information from one language to another. At this point in time, neither free nor commercial machine translation programs provide sufficiently accurate translations to rely upon for use with LEP patients in the healthcare arena. Further, the use of bilingual staff that are not trained or certified as translators should also be prohibited as the result is often poorly translated materials, which will discourage LEP individuals from trusting the information. Thus, entities should be prohibited from using machine translation to develop translated materials and instead utilize best practices as recognized by the American Translators Association (ATA) for translating documents. ATA offers a guide called “Getting it Right” that offers advice on what to look for when evaluating translation services. The Guide is available at https://www.atanet.org/docs/Getting_it_right.pdf.

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 other important aspects of accessibility for individuals with disabilities. For example, relying on providers to attest to their own accessibility is problematic because: (1) many providers do not have a good understanding of the scope of requirements for full accessibility, including accommodations for people with physical and mental disabilities; and (2) providers are required to be accessible under the Americans with Disabilities Act (and, by reference, these Medicaid managed care regulations) and so have a strong incentive to report compliance even if their setting may not be fully accessible. Both factors could lead to provider directories that have errors and misleading information if HHS allows managed care plans to rely solely on providers' attestations to determine accessibility.

California is a best practice state in this regard, as the MCOs and PIHPs must administer a 55-question accessibility survey to primary care providers and "high volume specialists" in their networks as part of their facility site review. Evidence suggests that the most accurate assessment would engage third party reviewers trained in accessibility issues to do site visits with participating providers as part of the certification process.[32] We recommend that HHS move toward requiring this kind of best practice as a standard policy for reviewing Medicaid providers either through the readiness review or certification and licensure process. If HHS is not willing to require third party review for accessibility, it should at least require managed care plans to incorporate an accessibility survey similar to California's as part of the network validation process. In this alternative, states would be required to directly test providers' attestations of accessibility through secret shopper surveys, site reviews, and/or similar mechanisms on a regular basis. This could be done through the EQR process to reduce costs to the state. In addition, the directory should encourage providers to indicate specific areas of expertise and training with regard to their overall accessibility.

The minimum requirements for physical accessibility are set forth in the ADA 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. Providers are supposed to already be meeting the minimum standards of accessibility, so the information that would be most valuable in the provider directory is whether the provider is more accessible than minimally required under these standards. We also suggest that providers be encouraged to indicate specific features, such as in physical structure or equipment, areas of expertise or training, or the types of disabilities they have experience accommodating. 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.

[32] J. Sanchez et al., *Perceived accessibility versus actual physical accessibility of healthcare facilities*, 25 REHABIL NURSING 6 (2000.)

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 ASL interpretation.

RECOMMENDATION: Amend section (h)(viii) as follows:

> (viii) Whether the provider's office/facility ***exceeds minimum physical accessibility requirements,*** including office~~s~~ ***buildings***, exam room(s), and equipment, ***and/or the provider has other accessible features, including structure, equipment, readily available auxiliary aides and services, or expertise, for people with disabilities.*** ~~is accessible for people with physical disabilities~~
>
> *i. § 438.10(i) - Information for all enrollees of MCOs, PIHPs, PAHPs, and PCCM entities: Formulary*

We strongly support HHS's 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.

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 available through the Marketplaces.

However, formulary tiering by cost in Medicaid is quite limited. Federal law allows only two cost sharing 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.[33]. A Medicaid enrollee's income determines the applicable level of cost sharing (as summarized in the chart below), with some populations and services exempt.[34]

[33] *See* 42 C.F.R. § 447.51.
[34] *See* 42 U.S.C. §§ 1396o, 1396o-1; 42 C.F.R. § 447.53.

Rules for Medicaid Prescription Drug Cost Sharing, January 2014			
	≤ 100% FPL	**101% - 150% FPL**	**>150% FPL**
Maximum Allowable Copayments			
Preferred drugs	$4	$4	$4
Non-preferred drugs[#]	$8 (nominal)	$8 (nominal)	20% agency cost of drug

[#] This cost sharing can also be applied to individuals normally exempt from cost sharing.

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 around coverage and authorization of services at § 438.210 and are explained to enrollees and potential enrollees.

RECOMMENDATION: Revise § 438.10(h)(4)(i)(2) by adding sections (A) – (E) as follows:

(2) What tier each medication is on. ***MCOs, PIHPs, PAHPs, and, when appropriate, PCCM entities, shall:***

(A) limit prescription drug cost-sharing to no more than two cost-sharing tiers (preferred/non-preferred) as described in 42 C.F.R. § 447.53;

(B) provide information on prior authorization requirements or other utilization management criteria, if applicable;

(C) make the exceptions process required under 42 C.F.R. § 483.3(s)(7) easily accessible;

(E) provide information on emergency prescription drug coverage and the available of a 72 hour supply required under 42 C.F.R. § 483.3(s)(6) and section 1927(d)(5) of the Act; and

(F) provide adequate notice and explanation to beneficiaries regarding access to non-preferred medications at preferred drug cost-sharing.

j. Additional Comments

We suggest that CMS add language to this section to ensure that managed care plans inform enrollees of their rights surrounding access to emergency and post stabilization care. We are aware of many cases where Medicaid managed care enrollees are unaware of their right to obtain emergency and post stabilization care out-of-network without prior authorization or additional cost-sharing. Too often these enrollees are inappropriately billed for emergency and post stabilization services by their plan or a provider. Enrollees may forgo other life necessities to pay enormous bills that they never should have received, or may suffer adverse financial impacts – such as being sent to collections, having the debt improperly reported to credit agencies, being sued in civil court for the debt, or having a lien placed against their wages or tax refund – due to the improper billing. For example, a recent court case against a California emergency room doctor found that the doctor repeatedly improperly billed consumers, resulting in civil debt collection actions against at least four consumers.[35] Unfortunately, too often, consumers do not know to complain about such improper billing – even when the consequences are dire – because they are not aware of their rights to receive emergency and post stabilization care out-of-network without prior authorization or additional cost-sharing. For this reason, we urge CMS to require states to ensure that consumers are informed of their rights regarding access to emergency and post stabilization services.

RECOMMENDATION: Add a new subsection (j) to § 438.10 as follows:

> § 438.10***(j) Emergency and post stabilization care. To enrollees and potential enrollees upon request, and to enrollees during enrollment and at least annually thereafter, each State (or at State option, each MCO, PIHP, PAHP, PCCM entity, and PCCM) must provide, in clear, accurate, and standardized form, information that describes or explains at least the following—***
>
> ***(1) What constitutes an emergency medical condition, emergency services, and post stabilization services, with reference to the definitions in § 438.114(a) of this chapter;***
>
> ***(2) The fact that prior authorization is not required for emergency services;***
>
> ***(3) The process and procedures for obtaining emergency services, including use of the 911 telephone system or its local equivalent;***
>
> ***(4) The locations of any emergency settings and other locations at which MCO, PIHP, PAHP, PCCM entity, and PCCM providers and***

[35] *See California v. Martello*, No. GCO47718 (L.A. Sup. Ct. May 29, 2012) (order granting preliminary injunction), *available at* http://wpso.dmhc.ca.gov/enfactions/docs/1869/1342638438857.pdf; *see also* Complaint at 9, *California v. Martello*, No. GCO47718 (L.A. Sup. Ct. Jul. 13, 2011), *available at* http://wpso.dmhc.ca.gov/enfactions/docs/1869/1372269027762.pdf.

hospitals furnish emergency services and post stabilization services covered under the contract;

(5) The enrollee's right to use any hospital or other setting for emergency care, subject to the provisions of § 438.114;

(6) The availability of post stabilization care services rules set forth at § 422.113(c) of this chapter; and

(7) The amount of cost sharing imposed, if any, for non-emergency services provided in an emergency department and the right to be notified of available non-emergency services providers, as set forth at 42 U.S.C. § 1396o-1.

Another issue of importance is ensuring that individuals with limited English proficiency or who are deaf or hard of hearing are able to interact with their plans to obtain needed information in a manner similar to English-speaking and hearing enrollees. With regards to any Call Center operated by a covered entity, we recommend that Medicaid MCOs comply with the same standards as QHPs in the Marketplaces. As finalized in the "Payment & Parameters" rule, QHP Call Centers must have telephonic interpretation available in at least 150 languages.[36] We strongly believe that the same rationale exists to require Medicaid managed care organizations to have telephonic interpreters in place for their Call Centers, particularly since the Medicaid MCOs have been subject to requirements to provide language services for decades pursuant to Title VI (as opposed to the newly created QHPs). Further, we recommend covered entities with Call Centers provide a TTD/TTY option to allow individuals who are deaf or hard of hearing to access information.

RECOMMENDATION: Add new subsection (k) to § 438.10 requiring Call Centers to provide oral interpretation.

(k) Call Center. If an MCO, PIHP, PAHP or PCCM operates a Call Center to address the needs of consumers requesting assistance regarding either plan operations or access to services, the Call Center must provide telephonic interpreter services in at least 150 languages. The Call Center must also provide a TTD/TTY option for individuals who are deaf or hard of hearing.

§ 438.12 - Provider discrimination prohibited

Medicaid enrollees should have access to comprehensive services from health providers, and providers participating in Medicaid managed care should be permitted to provide services according to the scope of their state licenses. We suggest that HHS further amend this section to make clear that Medicaid plans may not refuse to contract with providers because the provider offers services to which the health plan objects or engages in patient advocacy.. Further, HHS should make clear that Medicaid plans may

[36] 45 C.F.R. § 155.205(c).

not prohibit contracted providers from prescribing or providing services or treatments that are covered under the plan contract. For example, recently some Medicaid plans have set policies to only fill prescriptions for new hepatitis C medications such as Sovaldi when they are written by a particular heptolgist contracted with the plan. Other plan providers, including other heptologists, GI specialists, ID specialists, and even some experienced PCPs are equally qualified to prescribe these medications, and prescribing them falls squarely within their scope of practice under the law. HHS should explicitly clarify that any such policy constitutes reimbursement discrimination.

RECOMMENDATION: Amend § 438.12(a) as follows:

> (a) *General rules.* (1) An MCO, PIHP, or PAHP may not discriminate in the participation, reimbursement, or indemnification of any provider who is acting within the scope of his or her license or certification under applicable State law, solely on the basis of that license or certification, ***services the provider provides, or patient advocacy***. ***Discrimination in reimbursement includes limitations on which qualified contracted providers may prescribe a particular treatment or service.*** If an MCO, PIHP, or PAHP declines to include individual or groups of providers in its provider network, it must give the affected providers written notice of the reason for its decision.

SUBPART B

§ 438.52 - Choice of MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities

a. Restricting enrollees to a single PCCM entity

As proposed, § 438.52(a) allows states to restrict individuals who are required to enroll in a PCCM entity to a single entity. HHS noted that some states offer shared savings or other incentive payments to a PCCM entity and its participating providers, giving the PCCM entity "the same financial incentives as managed care plans."[37] In pursuit of shared savings or other incentive payments, a PCCM entity may want to limit enrollees to a particular network of providers and/or perform utilization review. If a PCCM entity is permitted to perform these functions, the entity will more closely resemble an MCO than a traditional PCCM, particularly from the enrollees' perspective. In those circumstances, Medicaid beneficiaries should have a choice of at least two PCCM entities for the same reasons that they have a choice of at least two MCOs. Enrollees need to have the ability to choose a managed care entity that will best meet their health needs. In short, if PCCM entities take on the majority of the characteristics of MCOs, HHS should treat them more like MCOs than like traditional PCCMs with respect to enrollee choice.

b. Ensuring access to reproductive health services

Managed care entities sometimes refuse to provide reproductive health services because they object to the services on moral or religious grounds. For example, in negotiating a managed care contract with a state, an MCO might request to have Medicaid-covered abortion services carved out of the contract, leaving enrollees to access those services outside of the MCO on a fee-for-service basis. Likewise, a PCCM that objects to abortions might refuse to refer an enrollee to an OB/GYN for abortion services. When Medicaid managed care entities refuse to provide reproductive health services, enrollees may encounter barriers to accessing these services in a timely manner. Many enrollees may not understand how to access services outside of the managed care entity and may have difficulty finding a provider to deliver these services. As a result, beneficiaries required to enroll in managed care need the ability to choose a managed care entity that will meet all of their reproductive health needs. As proposed, § 438.52 does not guarantee beneficiaries that ability.

RECOMMENDATION: Add § 438.52(a)(4) and amend § 438.52(b)(1) as follows:

> ***(a)(4) When a State restricts enrollees to two MCOs, PIHPs, PAHPs, or primary care case managers, or to a single PCCM entity, at least one of the MCOs, PIHPs, PAHPs, or primary care case managers and the single PCCM entity must provide the full range of reproductive health services covered***

[37] 80 Fed. Reg. 31098, 31163.

in the State plan, to the extent that reproductive health services fall within the scope of services for which the entity is responsible.

(b) *Exception for rural area residents*. (1) Under any managed care program authorized by any of the following, and subject to the requirements of paragraph (b)(2) of this section, a State may limit a rural area resident to a single MCO, PIHP, or PAHP: (i) A State plan amendment under section 1932(a) of the Act. (ii) A waiver under section 1115 of the Act. (iii) A waiver under section 1915(b) of the Act. ***The single MCO, PIHP, or PAHP must provide the full range of reproductive health services covered in the State plan, to the extent that reproductive health services fall within the scope of services for which the entity is responsible.***

c. Protections for rural area residents

Both the current and proposed § 438.52(b)(2)(ii) contains protections for rural area residents required to enroll in a single MCO, PIHP, or PAHP. We believe that these protections, which help to ensure that rural area enrollees have continuous access to all services covered under the state plan, should apply more broadly to all individuals enrolled in managed care. As a result, we propose removing these protections from § 438.52(b)(2)(ii) and integrating them into §§ 438.62 and 438.206 as appropriate.[38] Our discussion of §§ 438.62 and 438.206 below further explains this suggestion.

RECOMMENDATION: Amend § 438.52(b)(2)(ii) as follows:

ii) To obtain services from any other provider under any of the ~~following~~ circumstances ***set forth in § 438.62 and § 438.206(b)(3) – (b)(5).***

~~(A) The service or type of provider (in terms of training, experience, and specialization) is not available within the MCO, PIHP, or PAHP network.~~
~~(B) The provider is not part of the network, but is the main source of a service to the beneficiary, provided that—~~
~~(1) The provider is given the opportunity to become a participating provider under the same requirements for participation in the MCO, PIHP, or PAHP network as other network providers of that type.~~
~~(2) If the provider chooses not to join the network, or does not meet the necessary qualification requirements to join, the enrollee will be transitioned to a participating provider within 60 calendar days (after being given an opportunity to select a provider who participates).~~
~~(C) The only plan or provider available to the beneficiary does not,~~

[38] While we recognize that 42 U.S.C. § 1396u-2(a)(3)(B)(ii) directs the Secretary to establish circumstances in which rural area residents required to enroll in a single MCO, PIHP, or PAHP may receive services out-of-network, we believe that it is well within HHS' discretion to extend these protections to other Medicaid beneficiaries as well.

~~because of moral or religious objections, provide the service the enrollee seeks.~~
~~(D) The beneficiary's primary care provider or other provider determines that the beneficiary needs related services that would subject the beneficiary to unnecessary risk if received separately (for example, a cesarean section and a tubal ligation) and not all of the related services are available within the network.~~
~~(E) The State determines that other circumstances warrant out-of-network treatment.~~

§ 438.54 - Managed care enrollment

The enrollment and disenrollment processes are fundamental to ensuring access to appropriate health care, addressing continuity of care with existing providers, and ensuring ongoing access to health and mental health services. Managed care enrollees, however, have faced barriers when attempting to enroll in or disenroll from managed care plans or when seeking an exemption from mandatory managed care plan enrollment. We commend HHS for proposing rules to protect Medicaid enrollees and apply consistent and clear rules to both mandatory and voluntary managed care delivery systems. However, important protections are missing, and we therefore we provide recommendations below for further strengthening enrollment and disenrollment protections for consumers.

a. Voluntary and mandatory managed care delivery systems

In states with both voluntary and mandatory managed care delivery systems, we strongly support HHS's decision to require states with mandatory managed care programs to provide Medicaid enrollees with a period of fee-for-service coverage between their date of eligibility and their date of managed care enrollment. However, the proposed 14-calendar day election period (applicable to voluntary and mandatory managed care programs) is insufficient to ensure that enrollees are able to make informed decisions. Enrollees need sufficient time to research and compare their plan options. For some enrollees, this might also require enlisting a consumer counselor for help or communicating with doctors and other providers to ensure continuity of care. It is critical that enrollees are able to choose a plan that best meets their health and life needs, as they could be locked into that plan for up to one year. We therefore urge HHS to adopt a 45-calendar day election period. The 45-calendar day period should start 5, rather than 3, days after the notice specified in subsection (c)(3) is sent; 3 days is likely to be insufficient time for an enrollee to receive and open a mailing.

We also appreciate that HHS recognizes the importance of not only providing enrollees with sufficient time, but also sufficient information to make an appropriate plan selection. We strongly support HHS' proposal to ensure that enrollees have clear and timely information regarding plan enrollment and disenrollment. We recommend that states' informational notices explain not only the implications of not making a plan choice, but

the also the implications of making a plain choice (e.g., in states that limit disenrollment, that the enrollee can only disenroll without cause in the first 90 days, that after the 90 days they might need cause to disenroll; if the enrollee does not have cause to disenroll, they would be locked into their plan for up to 12 months, etc.). We further urge HHS to require states to include in the informational packets enrollment and disenrollment forms.

RECOMMENDATIONS: **1.** Amend § 438.54(c), applicable to voluntary managed care programs, as follows:

> (c)(2) A State must provide potential enrollees at least ~~14~~ ***45*** 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.
> . . .
>
> (3) The State must develop informational notices that clearly explain the implications to the potential enrollee of ***making and*** not making an active choice between managed care and FFS and declining the MCO, PIHP, PAHP, PCCM, or PCCM entity selected by the State, if relevant to the State's managed care program. These notices must:
>
> (i) Comply with the information requirements in § 438.10.
>
> (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.
>
> ***(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 beneficiary 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 beneficiary within three working days of receiving a telephone or written request for a form.***

2. Amend § 438.54(d), applicable to mandatory managed care programs, as follows:

> (d)(2) A State must provide potential enrollees at least ~~14~~ ***45*** calendar days of FFS coverage to provide the potential enrollee the opportunity to actively select their MCO, PIHP, PAHP, PCCM, or PCCM entity.
> (3) A State must provide informational notices to each potential enrollee that explain the process for enrolling in a MCO, PIHP, PAHP, PCCM or PCCM entity including the choice of MCOs, PIHPs, PAHPs, PCCMs or PCCM entities available, ***the implications to the potential enrollee of making and not making an active choice,*** how to make the enrollee's selection of a MCO, PIHP, PAHP or PCCM known to the State, and enrollee's right to disenroll within 90 days from the effective date of the enrollment. These notices must:
> > (i) Comply with the information requirements in § 438.10.
> > (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 (d)(2) of this section.
>
> ***(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 beneficiary 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 beneficiary within three working days of receiving a telephone or written request for a form.***

We support HHS's proposal to explicitly allow states to use additional fair and reasonable criteria to conduct the passive or default enrollment processes, so long as those criteria further continuity of care and coverage and seamless access to services and providers.

Further, we strongly support HHS's 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. In addition, enrollees should not be passively enrolled into a managed care plan that will not meet their reproductive health needs due to the plan's religious or moral beliefs.

RECOMMENDATIONS: 1. Amend § 438.54(a)(6) and (d)(6), as follows:

> **(a)(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 beneficiary has more than one existing provider of Medicaid services, the process should seek to preserve as many existing relationships as 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 beneficiary has more than one existing provider of Medicaid services, the process should seek to preserve as many existing relationships as possible.***

2. Add a new (b)(7)(ii) as follows:

> ***A beneficiary shall not be enrolled by default into an MCO or PCCM that refuses to cover all Medicaid services in the state plan.***

In states with mandatory managed care enrollment, enrollees – especially individuals with disabilities – should be able to obtain an exemption from the plan enrollment altogether to protect their access to continuity of care with an existing provider for ongoing treatment of a condition.

RECOMMENDATION: Add a new subsection (e) to ensure that enrollees can obtain an exemption from plan enrollment, if necessary.

> ***(e) Exemption from plan enrollment.***
>
> ***(1) General requirements. In States where mandatory enrollment in Medicaid managed care exists, States must allow eligible beneficiaries who satisfy the requirements in (i), (ii), or (iii) below, may request fee-for-service Medicaid for up to 12 months as an alternative to plan enrollment, by submitting a request for exemption from plan enrollment to the State agency as specified in (b) below.***
>
> ***(i) An eligible beneficiary who is an Indian as specified in §438.56(h), a member of an Indian household, or chooses to receive health care services through an Indian Health Service facility and has written acceptance from an Indian Health Service facility for care on a fee-for-service basis.***
>
> ***(ii) An eligible beneficiary who is receiving fee-for-service Medicaid treatment or services for a complex medical condition, from any provider who is participating in the Medicaid program but is not a contracting provider of a plan in the eligible beneficiary's county of***

residence, may request a medical exemption to continue fee-for-service Medicaid for purposes of continuity of care.

(A) Complex medical conditions. For purposes of this section, conditions meeting the criteria for a complex medical condition include, but are not limited to, the following:

(1) An eligible beneficiary is pregnant. A diagnosis of pregnancy in any trimester is per se proof of a complex medical condition for purposes of this section .

(2) An eligible beneficiary is under evaluation for the need for an organ transplant; has been approved for and is awaiting an organ transplant; or has received a transplant and is currently either immediately post-operative or exhibiting significant medical problems related to the transplant. Beneficiaries who are medically stable on post-transplant therapy are not eligible for exemption under this section.

(3) An eligible beneficiary is receiving chronic renal dialysis treatment.

(4) An eligible beneficiary has tested positive for HIV or has received a diagnosis of acquired immune deficiency syndrome (AIDS).

(5) An eligible beneficiary has been diagnosed with cancer and is currently receiving chemotherapy or radiation therapy or another course of accepted therapy for cancer that will continue for up to 12 months or has been approved for such therapy.

(6) An eligible beneficiary has been approved for a major surgical procedure by the fee-for-service Medicaid program and is awaiting surgery or is immediately post-operative.

(7) An eligible beneficiary has a complex neurological disorder, such as multiple sclerosis, a complex hematological disorder, such as hemophilia or sickle cell diseases, or a complex and/or progressive disorder not covered in (A) through (D) above, such as cardiomyopathy or amyotrophic lateral sclerosis, that requires ongoing medical supervision and/or has been approved for or is receiving complex medical treatment for the disorder, the administration of which cannot be interrupted.

(8) The beneficiary is enrolled in a Medicaid home and community-based waiver program under 42 U.S.C. §1915(c) or a State plan option under §1915(i) and

enrollment in a plan would jeopardize the beneficiary's ability to live in the community. Verification of participation in the waiver program or State plan option must be submitted with the disenrollment request by the beneficiary or the beneficiary's authorized representative as specified in § 438.56(f).

(B) A request for exemption from plan enrollment based on complex medical conditions shall not be approved for an eligible beneficiary who has: (i) Been a enrollee of either plan on a combined basis for more than 180 consecutive calendar days, (ii) A current Medicaid provider that the beneficiary is seeking to continue care with and was a main source of Medicaid services for the beneficiary during any time in the previous year who is contracting with another plan available to the beneficiary at the time the exemption is sought; or (iii) Has already begun treatment after the date of plan enrollment.

(iii) Except for pregnancy, any eligible beneficiary granted a medical exemption from plan enrollment shall remain with the fee-for-service provider only until the medical condition has stabilized to a level that would enable the individual to change physicians and begin receiving care from a plan provider without deleterious medical effects, as determined by a beneficiary's treating physician in the Medicaid fee-for-service program, up to 12 months from the date the medical exemption is first approved by the State agency. A beneficiary granted a medical exemption due to pregnancy may remain with the fee-for-service Medicaid provider through delivery and the end of the month in which 60 days post-partum occurs.

(iv) Any extension to the 12-month medical exemption time limit shall be requested through the State agency no earlier than 11 months after the starting date of the exemption currently in effect. The State agency will notify the beneficiary 45 days before the expiration of an approved medical exemption and will inform the beneficiary how to request an extension. An extension to the medical exemption shall be approved if the eligible beneficiary continues to meet the requirements of subsection (1).

(v) States may also provide exemptions to other populations, at their discretion.

(2) Process.

(i) A request for exemption from plan enrollment or extension of an approved exemption due to a complex medical condition, as specified in (above, shall be submitted to the State agency by the Medicaid fee-for-service provider or beneficiary or the Indian Health Service facility treating the beneficiary and shall be submitted by

mail or facsimile. Request for exemption from plan enrollment or extension of an approved exemption shall not be submitted by the plan.

(ii) The State agency (or its agent), shall approve each request for exemption from plan enrollment that meets the requirements of this section. At any time, the State agency may, at its discretion, verify the complexity, validity, and status of the medical condition and treatment plan and verify that the provider is not contracted or otherwise affiliated with a plan. State agency may deny a request for exemption from plan enrollment or revoke an approved request for exemption if a provider fails to fully cooperate with this verification. The State agency must accept the Statement of the treating physician or other qualified provider as true and valid and may not administratively overturn such a determination without evidence that it is not a valid medical exemption request.

(iii) Approval of requests for exemption from plan enrollment is subject to the same processing times and effective dates specified in section 438.56(e) for the processing of enrollment and disenrollment requests.

(iv) The State agency may revoke an approved request for exemption from plan enrollment at any time if the agency determines that the approval was based on false or misleading information, the medical condition was not complex as defined by this section, treatment has been completed, or the requesting provider is not or has not been providing services to the beneficiary. The State agency shall provide written notice to the beneficiary that the approved request for exemption from plan enrollment has been revoked and shall advise the beneficiary that he or she must enroll in a Medicaid plan and how that enrollment will occur, as specified in §438.56(f)(3). The revocation of an approved request for exemption from plan enrollment shall not otherwise affect an eligible beneficiary's eligibility or ability to receive covered services as a plan enrollee.

§ 438.56 - Disenrollment: Requirements and limitations.

a. Disenrollment requested by the MCO, PIHP, PAHP, or PCCM entity.

Federal rules currently prohibit a managed care plan from requesting that an enrollee disenroll because of a change in the person's health status or because of the person's utilization of services, diminished mental capacity, or uncooperative or disruptive behavior. However, we are concerned about provisions in the rule that allow managed care entities to involuntarily disenroll a person because the entity believes that the person's continued enrollment could seriously impair the entity's ability to furnish services to either this particular enrollee or other enrollees. This provision could create

opportunities for discrimination, particularly against individuals with mental health issues. We urge HHS to require states and plans to develop mechanisms for accommodating the unique needs of such individuals, including additional safeguards, so that they do not lose access to critical health coverage. Further, there continues to be a lack of clarity about prohibited grounds for requesting an enrollee disenroll from a plan. HHS should strengthen this rule to prohibit discrimination in disenrollment. Specifically, HHS should make clear that plans may also not discriminate against an enrollee because of the person's medical or mental condition or because of the enrollee's race, color, national origin, disability, age, sex, gender identity, or sexual orientation. This is particularly important in states with few plans.

RECOMMENDATION: Amend § 438.56(b) as follows:

> (2) 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).
> ***(3) Provide that the MCO, PIHP, PAHP, PCCM or PCCM may not request disenrollment because of an enrollee's race, color, national origin, disability, age, sex, gender identity, or sexual orientation.***

b. Disenrollment requested by the enrollee.

HHS' proposal to limit the 90-day without cause disenrollment period to the first 90 days of the *initial* enrollment is likely to interfere with access to care. There are many reasons that a managed care entity might not meet an enrollee's needs, and not all of those reasons will fall within the "for cause" grounds for disenrollment. For example, the managed care entity might provide poor quality care or there may be breakdown in the physician-patient relationship. Enrollees should be able to switch plans after enrolling if they realize soon after enrolling that the plan cannot, or will not, meet their needs, especially when the enrollee has other possible options. We strongly oppose HHS' proposal to limit enrollees to only one 90-day without cause disenrollment per enrollment period. Doing so is rule is likely to do more harm than good by forcing enrollees to stay in managed care plans that are not meeting their needs. We suggest that HHS also further amend this section to make clear that the 12-month period starts upon enrollment into the Medicaid managed care plan, not at the end of the 90-day period.

RECOMMENDATION: Amend § 438.56(c)(i) as follows:

(c) Disenrollment requested by the enrollee. If the State chooses to limit disenrollment, its MCO, PIHP, PAHP, PCCM and PCCM entity contracts must provide that a beneficiary may request disenrollment as follows: (1) For cause, at any time.

(2) Without cause, at the following times:

(i) During the 90 days following the date of the beneficiary's ~~initial~~ enrollment into a MCO, PIHP, PAHP, PCCM or PCCM entity, or the date the State sends the beneficiary notice of the enrollment, whichever is later.

(ii) At least once every 12 months ~~thereafter~~ ***after a beneficiary's ~~initial~~ enrollment into a MCO, PIHP, PAHP, PCCM or PCCM entity, or the date the State sends the beneficiary notice of the enrollment, whichever is later***.

(iii) Upon automatic reenrollment under paragraph (g) of this section, if the temporary loss of Medicaid eligibility has caused the beneficiary to miss the annual disenrollment opportunity.

c. When plans must disenroll an enrollee.

HHS should ensure that states and plans are clear not only on prohibited grounds for requesting disenrollment, but also on when states and plans *must* disenroll an enrollee.

RECOMMENDATION: Add the following subsections to §438.56:

(c) Reasons for disenrollment.

(1) The State agency or MCO, PIHP, PAHP, or PCCM shall disenroll any enrollee from a plan when one of the following conditions is met:

(i) An enrollee's Medicaid eligibility is terminated.

(ii) The State agency (or agent) incorrectly enrolled or assigned an enrollee to a plan not of his/her choosing, as indicated on the enrollment request form completed by the beneficiary.

(iii) An enrollee was enrolled in the plan due to incorrect information provided by the State agency or due to prohibited marketing practices by the plan.

(iv) An enrollee's request for disenrollment is due to plan merger.

(v) The request for disenrollment is based on a change of an enrollee's place of residence to outside the plan's service area.

(vi) An enrollee requests the disenrollment for any reason and the request is not made during any restricted disenrollment period for that enrollee.

(vii) An enrollee requests disenrollment for cause as defined in § 438,56(d)(2), when the request is made during any restricted disenrollment period for the enrollee.

(viii) An enrollee requests disenrollment for one of the reasons specified for exemption from plan enrollment in § 438.54 and meets the criteria specified in that section.
(ix) An enrollee requests and meets the criteria for expedited disenrollment.

(d) In a system in which enrollment in a plan is mandatory, the State shall provide enrollees with the information necessary to change their enrollment to another plan. An enrollee who does not select the competing plan shall be assigned another plan, in accordance with § 438.54. If a competing plan is at enrollment capacity, fee-for-service Medicaid shall be made available to the eligible beneficiary. Enrollees may disenroll from their plans into FFS Medicaid when they: (i) meet the criteria in § 438.54 for exemption from plan enrollment; (ii) are eligible for voluntary enrollment; or (iii) have good cause to disenroll as defined in § 438.56(d)(2)

d. Procedures for disenrollment

i. *Request for disenrollment*.

As HHS recognizes, the rate of enrollees that opt-out of Medicaid managed care is generally low. HHS' proposed rules appropriately seek to ensure that enrollees have adequate opportunities to make informed choices about their managed care plan. Critical to this scheme is ensuring that enrollees are able to disenroll as quickly and easily as possible from a plan that is not meeting their needs. HHS should thus establish specific requirements for states and plans regarding expedited requests for disenrollment.

RECOMMENDATION: Add the following provision to § 438.56(d)(1):

The beneficiary (or his or her representative) must submit an oral or written request, as required by the State—
(i) To the State (or its agent); or
(ii) To the MCO, PIHP, PAHP, PCCM or PCCM entity, if the State permits MCOs, PIHP, PAHPs, PCCMs and PCCM entities to process disenrollment requests.
(iii) Expedited disenrollment requests may be also submitted orally in-person or over the phone to the State agency (or its agent) or in writing by mail, facsimile, or via a dedicated website.

ii. *Cause for disenrollment.*

The situations that currently qualify for "cause" for disenrollment are too limited, especially since HHS' proposes to limit disenrollment without cause to only once per enrollment period (which, as stated above, we oppose). As a result, many enrollees are

unable to disenroll when they are not receiving the care that they need. For example, currently, enrollees do not have the right to disenroll from their managed care plan if a provider from whom they have been receiving care leaves their plan network. Such provider network changes could create disruptions in care and harm an enrollee's health and well-being. We applaud HHS for recognizing that such provider network changes can significantly impact enrollees in MLTSS programs, and codifying this as an additional cause for disenrollment. However, the adverse impact of provider network changes are not limited to individuals enrolled in MLTSS, and the rule should extend to all Medicaid enrollees. States and plans should also permit enrollees to disenroll when needed services are excluded from the plan's contract, when the provider network is inadequate to meet the beneficiaries' needs, and when there has been a breakdown in the physician-patient relationship. Finally, HHS should encourage states to address the specific types of problems arising in their state by making clear that states can also determine other reasons to constitute cause for disenrollment.

RECOMMENDATION: Amend § 438.56(d)(2) as follows:

(2) Cause for disenrollment. The following are cause for disenrollment:
(i) The enrollee moves out of the MCO's, PIHP's, PAHP's, PCCM's or PCCM entity's service area.
(ii) The plan does not, because of moral or religious objections, cover the service the enrollee seeks.
(iii) The enrollee needs related services (for example, a cesarean section and a tubal ligation) to be performed at the same time; not all related services are available within the provider network; and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk.
(iv) The enrollee requires Medicaid services that are excluded or unavailable from the plan and which can be obtained only if the member disenrolls from the plan.
~~(iv)~~ ***(v)*** For enrollees that use MLTSS services, the enrollee would have to change their residential, institutional, or employment supports provider based on that provider's change in status from an in-network to an out-of-network provider with the MCO, PIHP or PAHP.
~~(v)~~ ***(vi)*** Other reasons, including poor quality of care, lack of access to services covered under the contract (including lack of providers to deliver then) or lack of access to providers experienced in dealing with the enrollee's health care needs.
(vii) A provider from whom an enrollee has been receiving ongoing treatment or services leaves the plan network, resulting in disruption in care.
(viii) The enrollee requests the disenrollment because of an irreconcilable breakdown in the physician-patient relationship and has used the plan's problem resolution process. Documentation of the irreconcilable breakdown in the patient-physician relationship, including

the use of the plan's problem resolution process, must be submitted with the disenrollment request by the beneficiary, the beneficiary's authorized representative or the plan.
(ix) The enrollee meets the criteria in § 438.54(g) for exemption from plan enrollment.
(x) The enrollee or plan requests the disenrollment for any other reasons determined by the State agency to constitute good cause.

iii. 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: revise § 438.56(e) and add subsection (h) as follows:

§ 438.56(e)(1) Regardless of the procedures followed, the effective date of an approved disenrollment must be no later than the first day of the second month following the month in which the enrollee requests disenrollment or the MCO, PIHP, PAHP, PCCM or PCCM entity refers the request to the State**, *unless the disenrollment request is urgent and meets the criteria for an "expedited" disenrollment under paragraph (g)*.**
(2) If the MCO, PIHP, PAHP, PCCM, PCCM entity, or the State agency (whichever is responsible) fails to make the determination within the timeframes specified in paragraph (e)(1) of this section, the disenrollment is considered approved for the effective date that would have been established had the State or MCO, PIHP, PAHP, PCCM, PCCM entity complied with paragraph (e)(1) of this section.
(3) The MCO, PIHP, PAHP, or PCCM shall notify beneficiaries in writing of the approval or disapproval of enrollment and disenrollment requests, including expedited disenrollment requests, within no more than seven working days of receipt of the request (or less at state option). This notice shall include the effective date of the enrollment and/or disenrollment.

§ 438.56(h) Expedited disenrollment (new section). Approved expedited disenrollment requests shall be effective on the first day of the month in which the request is made. The State agency shall process all complete disenrollment requests as expedited disenrollments if they meet the following criteria and any required supporting documentation is provided:

(1) The beneficiary is an American Indian, a member of an American Indian household, or chooses to receive health care services through an Indian Health Service facility and has written acceptance from the Indian Health Service facility for care on a fee-for-service basis.
(2) The beneficiary is receiving services under a federal foster care or adoption assistance program or has been placed in the care of a child protective services agency. The disenrollment request must be submitted by the authorized foster parent, the authorized adoptive parent, or the licensed agency providing protective services.
(3) The beneficiary has a complex medical condition, specified in § 438.57, and the disenrollment request is submitted with verification of the medical condition, treatment plan, and duration of treatment by the Medicaid fee-for-service physician.
(4) The beneficiary is enrolled in a Medicaid home and community-based waiver program under 1915(c) or State plan option under 1915(i). Verification of participation in the waiver program must be submitted with the disenrollment request by the beneficiary or the beneficiary's authorized representative as specified in (h).
(5) The State agency incorrectly enrolled or assigned the eligible beneficiary to a plan not chosen by the beneficiary, as determined by the State agency, the beneficiary or the plan and verified by the State agency. An explanation of the incorrect enrollment or assignment must be submitted with the disenrollment request by the beneficiary or the beneficiary's authorized representative.
(6) The beneficiary submitted a non-expedited disenrollment request that meets the requirements for disenrollment or a request for exemption from plan enrollment based upon a qualifying complex medical condition that was not timely processed by the State agency. An explanation of the lack of timely processing must be submitted with the disenrollment request by the beneficiary or the beneficiary's authorized representative.
(7) The beneficiary has moved or been placed outside of the plan service area and has notified his or her caseworker of the new address. If the beneficiary's new address is not yet shown in the Medicaid Eligibility Data System, the beneficiary is responsible for requesting that the caseworker provide verification of the new address to the State agency by telephone, facsimile, or in writing.
(8) The beneficiary or plan has experienced an irreconcilable breakdown in the patient-physician relationship, has used the plan's internal grievance procedure, and the State agency has approved the disenrollment. Documentation of the irreconcilable breakdown in the patient-physician relationship, including the use of the plan's problem resolution process, must be submitted with the disenrollment request by the beneficiary, the beneficiary's authorized

representative as specified in (h), or the plan. Use of the plan's problem resolution process shall not be required in situations where a beneficiary's behavior presents physical risk to plan staff, a provider, or staff at a provider site, and the plan or provider has filed a police report regarding the physical risk.
(9) The beneficiary was enrolled in the plan due to incorrect information provided by the State agency or due to prohibited marketing practices by the plan, as determined by the State agency, the beneficiary or the plan and verified by the State agency. Explanation of the incorrect information or the prohibited marketing practices must be submitted with the disenrollment request by the beneficiary or the beneficiary's authorized representative.
(10) The beneficiary is deceased, and the death is not yet reflected in the Medicaid Eligibility Data System. A copy of the death certificate must be submitted with the disenrollment request by the beneficiary's authorized representative.

iv. *Notice and appeals.*

We commend HHS for recognizing that enrollees need to know about their disenrollment rights. We recommend that HHS amend § 438.56(f) to ensure that states and plans provides enrollees of disenrollment rights at application, enrollment, as well 60 days before the start of each reenrollment period.

RECOMMENDATION: Amend § 438.56(f)(1) as follows:

> Provide that enrollees and their representatives are given written notice of disenrollment rights ***at application, at enrollment, and*** at least 60 days before the start of each enrollment period.

§ 438.58 - Conflict of interest safeguards

We are concerned the conflict of interest provision is insufficient to address the various types of conflicts of interest that affect beneficiaries in Medicaid managed. Currently beneficiaries' opportunity to identify and request services is often improperly influenced by service authorization or financial management division of a managed care entity. Care coordination can be similarly affected. The lack of specific safeguards against conflicts of interest negatively affects beneficiaries because, among other issues, they are discouraged from requesting services, limited in choice, and discouraged from accessing the grievance system, including perceived retaliation from accessing that system. To help resolve such issues, we recommend that states' conflict of interest safeguards must have more specificity as to the conflicts they are expected to address, include sufficient disclosures to identify conflicts of interest, and provide a mechanism for remedial action. The proposed regulation, which is largely unchanged from the

current version, needs to be modernized to more specifically reflect the sources of conflict that have developed as Medicaid managed care has evolved.

RECOMMENDATION: Amend § 438.58 as (a) and adding section (b)-(c) as follows:

> ***(a)*** As a condition for contracting with MCOs, PIHPs, or PAHPs, a State must have in effect safeguards against conflict of interest on the part of State and local officers and employees and agents of the State who have responsibilities relating to the MCO, PIHP, or PAHP contracts or the enrollment processes specified in §438.54(b). These safeguards must be at least as effective as the safeguards specified in section 27 of the Office of Federal Procurement Policy Act (41 U.S.C. 423).
> ***(b) A State must ensure that a MCO, PHIP, or PAHP has sufficient conflict of interest safeguards to address conflicts related to identifying, requesting, and authorizing services; care coordination; and grievance systems.***
> ***(c) At a minimum, the conflict of interest safeguards must provide for***
> ***(1) Disclosure of relevant financial interests;***
> ***(2) A procedure to determine whether a conflict of interest exists and set forth a process to address any conflicts that arise; and***
> ***(3) Remedial action for failure to comply with the conflict of interest safeguards.***

§ 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's 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.

Too often, enrollees must disrupt long-standing relationships with their existing providers when they newly enroll in managed care or change plans, which can cause serious gaps in care that threaten the enrollee's health and well-being. For example, Bessy, a Medicaid beneficiary with high blood pressure, had been enrolled in a QHP with APTCs, but became newly eligible for Medicaid when she became pregnant. Bessy's OB/GYN from her QHP had delivered her other two children, and was also familiar with her high blood pressure and the risks it posed to Bessy during her pregnancy. Bessy wished to continue receiving prenatal care from her OB/GYN, but the OB/GYN did not contract with any of the Medicaid plans in her area. Bessy was forced to switch to a new OB/GYN when she was 15 weeks pregnant, and missed two prenatal appointments during the transition. In part because of the missed appointments, Bessy's blood pressure spiked, putting her and her baby at risk. She ended up having to get care in the emergency room. In another example, Gwen, a Medicaid beneficiary with diabetes, had to choose a managed care plan when her state moved seniors from FFS

Medicaid to managed care. She was on the verge of losing access to her long-time endocrinologist, who was familiar with her care and the multiple medications she took, because he did not contract with either of the plans from which Gwen could choose. Fortunately, the plan Gwen chose entered into a continuity-of-care agreement with her provider that allowed her to continue seeing him for several months and then safely transition to a plan provider. We share HHS's goal that these kinds of transitions should look like Gwen's case, and not like Bessy's.

We are concerned, however, that the proposed regulatory language in subsection (b)(1) will not fully achieve HHS's 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.

For example, in California, individuals who are found eligible for Medicaid after being enrolled in a Covered California plan may be directly enrolled into a Medicaid plan that contracts with their PCP, without ever spending time in FFS Medicaid. These individuals may nonetheless have important relationships with specialists who do not contract with their new Medicaid plan, and they should have access to the same transition protections as an enrollee coming into managed care from FFS. Similarly, where a person has been enrolled in a Medicaid managed care plan for many years and a key provider decides to leave the plan for reasons not related to quality of care, the enrollee should also be entitled to transition protections to the greatest extent feasible. These transitions are just as critical for enrollees' continuity of care as transitions from FFS to managed care, or between managed care plans, and the state's transition plan must apply to these circumstances, as well.

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. For example, an enrollee who wishes to continue seeing her current OB/GYN in order to maintain her current prenatal regimen is not necessarily at risk of a serious detriment to health or hospitalization or institutionalization if her treatment is disrupted,

but due to the time-sensitive nature of her care, continuity is particularly important. Similarly, a person who is receiving hospice care for a terminal illness may not meet the proposed threshold, but should not be forced to move to a new hospice facility simply because the her state is moving from FFS to managed care. A person who has waited several months for a scheduled surgery, should similarly not be forced to reschedule because her state is requiring her to move from one MCO to another a few weeks before her procedure is scheduled. 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***.
>
> *a. § 438.62(b)(1)(i)*

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's 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. For example, in June 2015 the California State Auditor released a report - California Department of Health Care Services Improved Monitoring of Medi-Cal Managed Care Health Plans Is Necessary to Better Ensure Access to Care. The report identifies major deficiencies in

beneficiary support, network access, and ineffective state monitoring. It provides crucial, objective information that can enable significant reform and improvement. Thus, we urge HHS to recognize the indispensable role of such independent monitoring – not only for managed care plans, but state agencies as well.

a. § 483.66(c)

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, which NHeLP recommends in § 438.3(s)(7).

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 and 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. (As discussed in our comments on § 438.358, we support requiring validation of network adequacy standards as a mandatory EQR activity and urge HHS to require EQR direct testing of network adequacy and timely access 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.[39] 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

[39] 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).

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 is 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.

We further recommend that such monitoring systems and the resulting reports include monitoring of disenrollments and the reasons for such disenrollments from health plans, whether initiated by the member or the health plan, as well as monitoring of denials of care, including partial denials of care (where the MCO has authorized less than the full amount of services requested by the treating provider).

RECOMMENDATION: Amend § 438.66(c) as follows:

> (c) 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:

We recommend HHS amend subsection (10) as follows:

> (10) 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).***

We also recommend HHS add new subsections (13 and 14) 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.***

We also recommend that HHS add new subsections (15) and (16):

> ***(15) Monitor disenrollments from MCO, PAHP, PHIP, or PCCM entities (including the reasons for these disenrollments),***
>
> ***(16) Monitor denials and partial denials of care by the MCO, PAHP, PHIP, or PCCM entity, and determine the validity of these denials and partial denials of care.***
>
> *b. § 438.66(d)*

We agree that states should conduct readiness reviews to determine capacity and compliance with federal requirements. These reviews should also include verifying that the MCO, PAHP, PHIP, or PCCM established a DURB required under § 438.3(s) and a member advisory committee required under § 438.110.

We support requiring on-site reviews in addition to desk reviews of documents, and agree that the state should conduct interviews with key staff. However, interviews with MCO leadership and staff may not provide a full picture of compliance efforts and will likely not identify deficiencies. Therefore, the readiness review on-site interviews should also include program staff responsible for implementing the program policies and procedures on a day-to-day basis, outside of the presence of the supervisor or administrator. We also strongly recommend that HHS require states to interview enrollees and other stakeholders, such as the Protection and Advocacy (P&A) organizations, legal services, consumer assisters, and other advocates as part of the readiness review.

HHS should also require follow up reviews to monitor compliance and identify backsliding and ongoing systems deficiencies. Such reviews should be conducted periodically, and without notice. The findings of the initial and follow up readiness reviews should be reported to the MCAC, LTSS stakeholder group for comment, and included in the annual report required under § 438.66(e).

RECOMMENDATION: Add a new subsection to § 483.66(d)(1)

> ***(vi) When the state enters into or renews a contract with a MCO, PAHP, PHIP, or PCCM entity, with a follow-up compliance review conducted not less than once during the term of the contract.***

Amending subsection to § 483.66(d)(3) as follows:

> (3) Readiness reviews must include both a desk review of documents and on-site reviews of each MCO, PIHP, PAHP or PCCM entity. On-site reviews must include interviews with MCO, PIHP, PAHP or PCCM entity staff and leadership that manage key operational areas. ***On-site interviews shall also include***

program staff responsible for implementing the program policies and procedures on a day-to-day basis, outside of the presence of the supervisor or administrator. The state must also interview enrollees and other stakeholders, such as the Protection and Advocacy (P&A) organization, legal services, consumer assisters, and other advocates.

Amending subsection § 483.66(d)(4) as follows:

(4) A State's readiness ***and follow up*** review must assess the ability and capacity of the MCO, PIHP, PAHP and PCCM entity (if applicable) to perform satisfactorily for the following areas:

Adding new subsection (G) to § 483.66(d)(4)(i)

(G) DUR activities and member advisory committee operations.

c. *§ 483.66(e)*

As proposed, the minimum content of the program report does not encompass the full range of monitoring activities required under subsections (b) and (c). We are concerned that states may not adequately conduct performance monitoring and data collection and analysis activities that are not required to be included in the program report. Moreover, the program report must address all the performance areas to provide states, policy makers, and stakeholders with as a complete pictures as possible of the managed care operations, performance, and compliance. Therefore, we recommend that HHS require a full annual program report showing the monitoring activities and results. In addition, HHS should require consultation with the MCAC, LTSS stakeholder group, and the members' advisory group for comments prior to the release of the final report.

RECOMMENDATION: Amend subsection § 438.66(e)(2) as follows:

2) The program report must provide information on and an assessment of the operation of the managed care program, and include, at a minimum, ***performance areas and data as described in subsection (b) and (c)***, and the following:

Amend § 438.66(e)(3) as follows:

(3) The program report required in this section must, ***no less than 30 days prior to submitting the report to CMS, be***:

~~(i) Posted on the Web site required under § 438.10.~~

(~~i~~ii) Provided to the Medical Care Advisory Committee, required under § 431.12 of this chapter.

(~~ii~~iii) Provided to the stakeholder consultation group specified in § 438.70, to the extent that the managed care program includes LTSS.

(iii) Provided to the member advisory committee specified under §

438.110; and

(4) The program report required in this section must be posted to the state website required under § 438.10 no later than three calendar days following the submission of the report to CMS required under subsection (1).

§ 438.68 - Network adequacy standards

We strongly support HHS' addition of this new section on network adequacy. For too long, the Medicaid managed care program has lacked specific network adequacy standards aimed at ensuring that consumers can access care from their Medicaid plans. These proposed provisions add significant detail to guide states and Medicaid plans in developing their networks to ensure adequacy. We appreciate HHS's attention to the network needs of LTSS. We encourage HHS to monitor this area closely and to facilitate state's sharing best practices as they implement new standards for LTSS networks and monitor their contracted plans.

We also commend HHS for requiring plans to publish their network adequacy standards . We agree that this is an area where transparency is very important, and consumers, providers, advocates, and other stakeholders must have ready access to the standards to which plans are being held. We suggest that HHS also compile this information and publish it on Healthcare.gov or Medicaid.gov on an annual basis, since many stakeholders may look for this information on a federal government website rather than looking on the Web site for their state Medicaid program.

We strongly support HHS' decision to consider a variety of existing network adequacy standards, including Medicare Advantage standards, and the standards for QHPs in the Marketplaces, in deciding what approach to take to these Medicaid managed care rules. In general, the Marketplace approach to network adequacy sets very broad and unspecific standards, while the MA approach is highly technical and specific with respect to travel time and distance, and provider-patient ratios. We appreciate that, in these proposed rules, HHS attempts to strike a balance between these two extremes, by setting forth specific areas that states and plans must account for, but not requiring a granular level of detail for every possible specialist type. HHS has requested comment on this approach, and asked whether HHS should instead set national standards. 80 FR 31145. We urge HHS to set national standards. By permitting each state to set its own time and distance standards without any outside limits set by HHS, we are concerned that access will be inadequate, standards will vary too widely from one state to another, and oversight by HHS will continue to be fragmented. [40] Prescriptive national

[40] SUZANNE MURRIN, DEPT. OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GENERAL, STATE STANDARDS FOR ACCESS TO CARE IN MEDICAID MANAGED CARE 8-9 (2014) ("CMS and States need to do more to ensure that all States have adequate access standards and strategies for assessing compliance."), *available at* http://oig.hhs.gov/oei/reports/oei-02-11-00320.pdf; *see also, e.g.,* ABBI COURSOLLE, NAT'L HEALTH LAW PROG., MEDICAID MANAGED CARE MODEL PROVISIONS: NETWORK ADEQUACY, (2014), *available at* http://www.healthlaw.org/issues/medicaid/managed-care/medicaid-managed-Care-model-provisions-

standards, like those used in Medicare Advantage, are appropriate in the Medicaid context, given the low-income and high need population served by the program. As described in more detail below and in our comments to §§ 438.206-.207, we suggest that HHS adopt specific minimum standards in the areas of geographic access, provider-patient ratios, and timely access to care.

We appreciate that HHS wishes to preserve state flexibility with respect to network adequacy, and not create additional burdens on states and plans by prescribing standards that are so stringent that few plans can comply. Currently, however, the majority of states already hold their plans to specific quantitative network adequacy standards in at least some areas. Thus, we do not believe that HHS's setting a national floor for states will create such a burden, but will instead provide consistency and continuity for enrollees even as administrations change, and will ensure that enrollees in all states are held to basic standards regarding access. The standards we have proposed are largely in line with what already exists at the state level, but will ensure greater consistency across borders. We encourage HHS to work with states that have higher standards in place to maintain those standards in light of new federal minimums.

a. § 438.68(b)(1) – Provider Specific Standards

We are pleased that HHS will, for the first time, require states to employ specific measures of travel time and distance to determine whether the networks of their contracted plans are adequate. We commend HHS for delineating in this section the provider types for which states must develop geographic access standards. We applaud HHS for capturing key provider types for the foundation of a network for any comprehensive Medicaid managed care plan.

However, stronger standards are needed to ensure that women can access the full range of reproductive health care services. Freedom of choice, while a critical protection, is not a substitute for a network of providers that can meet the unique health needs of women enrollees. We accordingly support requiring that states establish separate network adequacy standards for access to OB/GYNs, but urge HHS to broaden the rule, which is too narrow as currently written. A plan's provider network must be sufficient to ensure that women have meaningful access to all covered family planning and abortion services. HHS' narrow focus on OB/GYNs will fail to ensure the adequacy of a plan's network in this regard. We therefore urge HHS to broaden the category currently titled "OB/GYN" to "providers of women's health care services," to capture a broader scope of practitioners who offer such services, which include prenatal care, family planning counseling and treatment, abortion services, and screening and treatment for vaginal infections and STIs. Since, in many states, these services are performed by Family Practitioners, Nurse Practitioners, Certified Nurse Midwives, and

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issue-3 (describing various state standards for travel time and distance, ranging from 5 miles in two states, to 100 miles in two other states).

other provider types, a more expansive category will better capture the adequacy of a plan's network.

Additionally, timely access standards should include all levels of maternal care, as defined by the American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine's, *Obstetric Care Consensus: Levels of Maternal Care*.[41] An increasing number of the 45% of Medicaid-financed births occur in managed care. It is critical that pregnant women enrolled in Medicaid managed care have access to the most appropriate level of maternity care, including routine prenatal care and/or specialty case as needed, to ensure healthy birth outcomes healthy babies.

We also suggest that HHS make clearer plans' obligations when no provider is available within the state's standard network. In such cases, we suggest plans must be required to either arrange for care to be provided by a geographically proximate provider who is out-of-network, provide transportation for the enrollee to travel to see an in-network provider who is located beyond the maximum travel time or distance, arrange for a provider to travel to the enrollee or a designated location that is geographically proximate to the enrollee's home or workplace, or provide telemedicine. Currently, even in some states with robust geographic access standards, plans have little accountability to ensure care when they are not able to meet the standard. We recognize that it will be difficult for plans to meet the standard in some regions, due to provider shortages, existing travel patterns, or other factors. But too often, where the Medicaid plan is granted an alternate access standard in those regions, the alternate access standard becomes a "no access" standard, since plans are exempted from the prevailing standard but not required to use alternative methods to ensure that enrollees have access to care. We urge HHS to explicitly require states to ensure that *all* enrollees have access, even if they fall within the 10% of enrollees whose residence or workplace is not within the designated geographic area, or if the plan has been exempted from the standard.

RECOMMENDATION: Amend § 438.68(b)(1) as follows:

> *Provider-specific network adequacy-standards*. (1) At a minimum, a State must develop time and distance standards for the following provider types, if covered under the contract ***that meet or exceed the following***:
>
> (i) Primary care, adult and pediatric***, is available within 30 minutes or 15 miles of the residences or workplaces of 90% of enrollees***.
>
> (ii) ***Women's health care services, including family planning, prenatal care, and abortion services, which may be provided by*** OB/GYN***s, Family Practitioners, Nurse Midwives, Nurse Practitioners, Physician***

[41] Am. Coll. of Obstetricians & Gynecologists & Soc'y for Maternal-Fetal Medicine, *Obstetric Care Consensus: Levels of Maternal Care. No. 2* (Feb. 2015), http://www.acog.org/Resources-And-Publications/Obstetric-Care-Consensus-Series/Levels-of-Maternal-Care.

Assistants, and other providers, are available within 60 minutes or 30 miles of the residences or workplaces of 90% of enrollees.
(iii) Behavioral health***, adult and pediatric, is available within 30 minutes or 15 miles of the residences or workplaces of 90% of enrollees***.
(iv) Specialist, adult and pediatric***, is available within 60 minutes or 30 miles of the residences or workplaces of 90% of enrollees***.
(v) Hospital***, is available within 30 minutes or 15 miles of the residences or workplaces of 90% of enrollees***.
(vi) Pharmacy***, is available within 30 minutes or 15 miles of the residences or workplaces of 90% of enrollees***.
(vii) Birth center, is available *within 60 minutes or 30 miles of the residences or workplaces of 90% of enrollees.*
(vii) Pediatric dental***, including dental sealants and fluoride varnish for enrollees under age 21, is available within 30 minutes or 15 miles of the residences or workplaces of 90% of enrollees***.
(viii) Indian Health Care Providers, as defined in § 438.14(a), are available within 60 minutes or 30 miles of the residences or workplaces of 90% of Indian enrollees, as defined in § 438.14(a).
(~~viii~~***ix***) Additional provider types when it promotes the objectives of the Medicaid program, as determined by CMS, for the provider type to be subject to time and distance access standards.
(x) Whenever medically necessary care is not available within the state's standard for travel time or distance, the MCO, PIHP or PAHP shall arrange for the enrollee to receive medically necessary care by:
(A) Arranging for the enrollee to see an out-of-network provider;
(B) Providing transportation, including the costs of food, lodging, and attended, when necessary, to a contracted provider to whom travel exceeds the standard;
(C) Arranging for a provider to travel to the enrollee or a designated location that is within the state's standard for travel time and distance; or
(D) Where medically appropriate, arranging for telemedicine.

b. § 438.68(b)(2)

For the same reasons that we believe they are necessary in other types of services, we strongly recommend that HHS establish national network adequacy standards for LTSS, including standards that apply to situations where the beneficiary travels to the provider, as well as standards for situations where an LTSS provider travels to the beneficiary in a home or community setting. At the same time, we recognize that there are few models to draw from and little research upon which to base specific recommendations. Accordingly, we urge HHS to track and evaluate the state development and enforcement of these standards. We agree that standards other than time and distance

may be more appropriate for certain types of LTSS, such as where the provider travels to the individual. However, we would recommend that such alternative types of standards not be limited to provider types that travel to the beneficiary as they may also be appropriate for other LTSS, such as residential services.

Further, we recommend that HHS convene a group of experts and interested parties to formulate these recommendations. Within 6 months of finalizing these regulations, HHS should convene a working group to formulate specific time and distance standards for LTSS, standards for LTSS provider types that travel to the enrollee to deliver services, and mechanisms to measure and enforce timeliness and reliability standards for such providers. Membership should include representatives from HHS, including CMS, SAMSA, and OCR; state Medicaid agencies; managed care plans; Medicaid beneficiaries and Medicaid beneficiary advocates; and academics. HHS should use the findings of this group to develop standards for LTSS that will be set forth in sub-regulatory guidance, similar to the way that HHS sets out network adequacy standards for Medicare Advantage plans on an annual basis.

RECOMMENDATION: Amend § 438.68(b)(2) as follows:

(i) States with MCO, PIHP or PAHP contracts which cover LTSS must develop:
(A) ~~Time and distance~~**Network adequacy** standards, **including time and distance standards, that meet or exceed standards established by the Secretary** for LTSS provider types in which an enrollee must travel to the provider to receive services; and
(B) Network adequacy standards other than time and distance standards **that meet or exceed standards established by the Secretary** for LTSS provider types that travel to the enrollee to deliver services.

c. § 438.68(b)(3) – Timely Access standards

We appreciate that HHS will continue to require plans to meet standards for timely access to care in § 438.206. We recommend, however, that HHS's approach set a floor for specific appointment wait times that plans may not exceed. We suggest that HHS set such standards in this section, in order to place all specific network adequacy standards in one section of the regulation. HHS should add these standards to paragraph (b)(3) and re-designate current paragraph (b)(3) and (b)(4). HHS should also clarify that the scope requirements in newly designated (b)(4) apply to the standards at new paragraph (b)(3) as well as paragraphs (b)(1) and (b)(2).

Currently, a majority of states set specific, quantitative appointment wait time standards for their Medicaid plans.[42] However, those state standards vary quite significantly.[43] This

[42] MURRIN, *supra* note 40 at 9 (finding that 31 states have such standards in place).

variation means that enrollees in different parts of the country will have very different experience in terms of appointment wait times, and will also make HHS's task in supervising the state's monitoring of their contracted plans more challenging. A study last year by HHS' Inspector General found only half the doctors listed in official plan directories were taking new Medicaid patients; among those doctors who were, one-fourth could not see patients for a month.[44] We urge HHS to set a national floor for appointment waiting times, as delineated in our recommendations below to avoid this kind of delay. Our recommendations are adapted from regulations implementing California's Knox-Keene Act.[45]

Timely access to family planning, abortion, and prenatal care services is particularly critical. HHS should thus establish additional standards to ensure that Medicaid managed care enrollees can access these services without unreasonable delay. For prenatal care, time standards should be based on trimester of pregnancy. Because of the wait time restrictions imposed by many states, it is essential that women be able to make an initial appointment for termination as early as possible to avoid more complicated procedures.

We also recommend that HHS consider requiring plans to provide a 24-hour telephone line to provide triage or screening services. These telephone lines are commonly used in the private insurance market and studies have found that they are associated with reductions in inappropriate use of emergency services.[46] We believe that by requiring plans to use some kind of telephonic screening system that is available 24/7, HHS can improve access to care by helping enrollees to quickly determine what level of care they need.

Further, we urge HHS to adopt standards for in-office wait times. Too often, Medicaid managed care enrollees schedule a needed appointment, arrange necessary transportation and child care and take time off of work in order to attend it, and then wait hours after their schedule appointment time before they see a provider. These long in-office wait times can seriously disrupt the fragile arrangements that the enrollee has made in order to attend the appointment. In some cases the enrollee will not be able to wait any longer for an appointment and must reschedule the appointment, further delaying care.

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[43] *Id.*

[44] DANIEL R. LEVINSON, DEPT. OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GENERAL, ACCESS TO CARE: APPOINTMENT AVAILABILITY IN MEDICAID MANAGED CARE 9-10 (2014).

[45] See CAL. CODE REGS., tit. 28, § 1300.67.2.2(c).

[46] *See, e.g.,* Elena Bissell et al., *Effectiveness of a 24/7 Nurse Advice Line in Reducing Non-Emergent Visits to the Emergency Room in Rural New Mexico*, 58 J. INVESTIGATIVE MED. 126 (2010); Gregory M. Bogdan et al., *Evaluating Patient Compliance With Nurse Advice Line Recommendations and the Impact on Healthcare Costs*, 10 AM. J. MANAGED CARE 534 (2004); Steven R. Poole et al., *After-Hours Telephone Coverage: The Application of an Area-Wide Telephone Triage and Advice System for Pediatric Practices,* 92 PEDIATRICS 670 (1993).

Finally, we also encourage HHS to set standards for and require states to monitor calls to Medicaid plans customer service lines. Too often, enrollees who cannot find a provider, need assistance with transportation, or who wish to file a grievance languish on hold with their plan's telephone line for hours, or are unable to get through on the line at all. HHS should set minimum standards to ensure that telephone wait times are reasonable so that enrollees' can address problems with their plans.

RECOMMENDATION: Amend § 438.68(b) as follows:

(3) Timely access. Each MCO, PIHP, and PAHP must meet and require its network providers to meet the following standards for timely access to care and services, taking into account the urgency of the need for services:

(i) Urgent care appointments for medical or dental services shall be available within 48 hours of the request for appointment, except as provided in (ix);

(ii) Non-urgent appointments for primary and specialty care shall be available within 15 business days of the request for appointment, except as provided in (ix) and (x);

(iii) Non-urgent appointments with a non-physician mental health care provider shall be available within 10 business days of the request for appointment, except as provided in (ix) and (x);

(iv) Non-urgent appointments for ancillary services for the diagnosis or treatment of injury, illness, or other health condition shall be available within 15 business days of the request for appointment, except as provided in (ix) and (x);

(v) Non-urgent dental appointments shall be offered within 30 business days of the request for appointment, except as provided in (ix);

(vi) Prenatal care appointments shall be offered within 5 business days of the request for appointment, except that if the pregnant woman is in her second or third trimester of pregnancy and has not yet initiated prenatal care, prenatal care appointments should be available within 1 business day of the request for the appointment;

(vii) Abortion care appointments for women in their first trimester of pregnancy shall be made available within 3 business days of the request for appointment; abortion care appointments for women in their second trimester of pregnancy or beyond shall be made available within 1 business day of the request for appointment;

(viii) Family planning care appointments shall be available within 5 business days of the request for appointment;

(ix) The applicable waiting time for a particular appointment may be extended if the referring or treating licensed health care provider, or the health professional providing triage or screening services, as applicable, acting within the scope of his or her practice and consistent with professionally recognized standards of practice, has

determined and noted in the relevant record that a longer waiting time will not have a detrimental impact on the health of the enrollee;
(x) The applicable waiting time for a particular appointment must be shortened if the referring or treating licensed health care provider, or the health professional providing triage or screening services, as applicable, acting within the scope of his or her practice and consistent with professionally recognized standards of practice, has determined that it is medically necessary for the enrollee to receive care more quickly.
(xi) Each MCO, PIHP, and PAHP shall provide or arrange for the provision, 24 hours per day, 7 days per week, of triage or screening services by telephone.
(A) Each MCO, PIHP, and PAHP shall ensure that telephone triage or screening services are provided in a timely manner appropriate for the enrollee's condition, and that the triage or screening waiting time does not exceed 30 minutes.
(B) A MCO, PIHP, and PAHP may provide or arrange for the provision of telephone triage or screening services through one or more of the following means: plan-operated telephone triage or screening services; telephone medical advice services; the plan's contracted primary care and mental health care provider network; or other method that provides triage or screening services consistent with the requirements of this subsection.
(xii) For routine, preventive, and non-urgent appointments, the in-office waiting time from the time of a scheduled appointment shall not exceed 30 minutes in length; if the wait time must be prolonged do to exigent circumstances, the provider's office staff shall provide the enrollee with an explanation for the delay and make an offer to reschedule the appointment;
(xiii) The state shall require that for each MCO, PIHP, and PAHP, during normal business hours, the waiting time for an enrollee to speak by telephone with a plan customer service representative who is knowledgeable about and competent to respond to an enrollee's questions and concerns shall not exceed ten minutes.

(~~3~~***4***) *Scope of network adequacy standards.* Network adequacy standards established in accordance with paragraphs (b)(1)***,*** ~~and~~ (b)(2)***, and (b)(3)*** of this section must include all geographic areas covered by the managed care program or, if applicable, the contract between the State and the MCO, PIHP or PAHP. States are permitted to have varying standards for the same provider type based on geographic area ***as long as they comply with the minimum standards established in the paragraphs above***.

d. § 438.68(c)(1) – Development of standards

We appreciate that HHS has moved much of the language from existing § 438.206(b)(1) to this section, to clarify that states must account for these factors in developing their time and distance standards. We especially commend HHS for expanding these provisions to more specifically account for language access, cultural competency, and access by individuals with disabilities. These additions will go a long way toward ensuring that states and plans account for the needs of all enrollees, and that plan networks are explicitly designed to be accessible for LEP enrollees, enrollees with diverse backgrounds, and those with disabilities.

We recommend two changes to this section. First, we suggest that HHS add a provision to this section that requires states to ensure that contracted plans comply with specific provider-patient ratios for adult and pediatric primary care. We appreciate that it may not be appropriate for HHS to mandate specific ratios for all provider types in Medicaid managed care, as it does in Medicare Advantage. In general, we agree with HHS that, given the wide variation in terms of demographics of the Medicaid managed care population from state to state, such standards are better left to the states. We suggest, however, that primary care is the common denominator among all populations and plans, and is the key to making managed care work for enrollees. Thus, we urge HHS to set a national floor with which states ensure compliance to ensure that enrollees have adequate access to primary care providers.

Second, we suggest that HHS add detail to its provision on calculating the geographic locations of providers and enrollees. We commend HHS for keeping the general structure of this provision, which requires states to consider the means of transportation that Medicaid enrollees use in calculating geographic access standards. We recommend that HHS add more specific language to this section to clarify that in areas where most Medicaid enrollees rely on public transportation, the geographic access standard account for public transportation travel times and routes. In certain regions of the country, an enrollee may have to take three busses and travel a total distance of fifty miles to reach a destination that is only twenty miles away as the crow flies. In many urban areas, taking public transit to reach a location that is only 15 or 20 minutes away by car will take well over an hour during normal business hours. In order to achieve HHS's intent of ensuring that enrollees who use public transportation are not disproportionately disadvantaged by a state's geographic access standards, we urge HHS to add language to clarify that transit routes and schedules must be accounted for. Similarly, we suggest that HHS add language to this section to require states to account for foreseeable road closures. In many mountainous regions of the country, roads close regularly in the winter due to snow and ice. A destination that is only half-an-hour away during the summer months when mountain roads are open could require over two hours of travel to reach when those roads are closed and the enrollee must use an alternate route. Similar issues occur in certain low-lying regions in the summer due to flooding. In states where such closures are foreseeable, the state should account for these closures in developing a geographic access standard.

RECOMMENDATION: Amend § 438.68(c)(1) as follows:

> (c) *Development of network adequacy standards.* (1) States developing network adequacy standards consistent with subdivision (b)(1) ***and (b)(3)*** of this section must consider, at a minimum, the following elements:
>
> (i) The anticipated Medicaid enrollment.
>
> (ii) The expected utilization of services.
>
> (iii) The characteristics and health care needs of specific Medicaid populations covered in the MCO, PIHP, and PAHP contract.
>
> (iv) The numbers and types (in terms of training, experience, and specialization) of network health care professionals required to furnish the contracted Medicaid services. ***At a minimum, the State shall ensure that each MCO, PIHP, or PAHP contracts with one adult primary care provider for each 1200 adult enrollees, and one pediatric primary care provider for each 1000 enrollees under 21.***
>
> (v) The numbers of network health care professionals who are not accepting new Medicaid patients.
>
> (vi) The geographic location of health care professionals and Medicaid enrollees, considering distance, travel time, the means of transportation ordinarily used by Medicaid enrollees. ***If the majority of Medicaid enrollees in the service area of a MCO, PIHP, or PAHP use public transportation, the travel times and distances must be calculated based on public transportation schedules and routes. Similarly, if roads are frequently closed in the region due to weather, the travel times and distances must account for potential road closures.***

e. § 438.68(d) – Exceptions process

We appreciate that HHS has provided for an exceptions process that will permit states to grant an exception in the rare case that the plan simply cannot comply with the standard set pursuant to § 438.68. HHS has specifically requested comment on these provisions. *See* 80 FR 31146. While instances where plans cannot comply with network adequacy standards should not be common, we recognize that there are certain rural and sparsely populated areas where provider access can be very difficult for individuals with any form of health coverage. In addition, in some regions, there are serious provider shortages that will hinder compliance. We commend HHS for requiring in § 438.68(d)(1)(ii) that states evaluate the number of practicing health care professionals in the service area before granting an exception to make sure that the exception is warranted. In addition, we suggest that HHS refer to the requirements for alternate access we set forth at our proposed paragraph (b)(1)(x) of this section, to ensure that any plan who is granted an exception to the state's standard has a plan in place to ensure that enrollees will still be able to get needed care while the plan is under an approved exception.

RECOMMENDATION: Amend § 438.68(d)(1) as follows:

(d) *Exceptions process.* (1) To the extent the State permits an exception to any of the provider-specific network standards developed under this section, the standard by which the exception will be evaluated and approved must be:

(i) Specified in the MCO, PIHP or PAHP contract.

(ii) Based, at a minimum, on the number of health care professionals in that specialty practicing in the MCO, PIHP, or PAHP service area.

(iii) Require the MCO, PIHP, or PAHP to comply with the paragraph (b)(1)(x) of this section.

(2) States that grant an exception in accordance with paragraph (d)(1) of this section to a MCO, PIHP or PAHP must monitor enrollee access to that provider type on an ongoing basis and include the findings to CMS in the managed care program assessment report required under § 438.66.

§ 438.70 - Stakeholder engagement when LTSS is delivered through a managed care program

We strongly support HHS' proposal to require states to develop state-level LTSS stakeholder advisory committees, recognizing that enrollees and other stakeholders can play a critical role in the success of a MLTSS program. However, we strongly disagree with HHS' proposal to allow states flexibility in the design and implementation of LTSS stakeholder groups. The "sufficiency" standard proposed by HHS is too broad and too vague to allow for meaningful and sustained stakeholder engagement.

State agencies and MCOs have a poor track record engaging consumers and other stakeholders in program in planning, implementation, and oversight. Currently, every state Medicaid program must have a Medical Care Advisory Committee (MCAC). 42 C.F.R. § 431.12. Yet, the transparency, functionality and effectiveness of MCACs vary widely. For example:

- Pennsylvania's Medical Assistance Advisory Committee (MAAC) is often cited by NHeLP and other advocates as a model for other states by providing support for consumer participants and transparency, including full posting of membership, meeting times, by-laws, and training materials.

- The District of Columbia has not updated its MCAC page for more than a year and provides no information on meeting times or opportunities for stakeholder participation. The most current enrollment information listed on the MCAC page dates from 2012.

- Tennessee's Medicaid program, TennCare, provides no mention of the state's MCAC on its website. Advocates report that there is no MCAC currently in operation in Tennessee.

We recommend that HHS establish detailed requirements for state LTSS stakeholder groups, with clear requirements for membership, operations, responsibilities, and transparency. HHS should improve and strengthen standards already in effect for MCACs, and also look to other HHS advisory bodies. For example, in response to complaints from HIV/AIDS activists, Congress established minimum requirements for membership, conflict of interest, and transparency for the Part A Planning Councils under the Ryan White Act.[47] Robust standards, and HHS compliance monitoring and enforcement, will help ensure that consumer stakeholder groups can function as intended, as vital partners in program development and oversight. These include requirements for:

- Membership, including minimum requirements for Medicaid enrollees, consumer coalitions, legal services providers, and other community stakeholders
- Transparency, including public posting of meeting times, agenda, by-laws, membership, minutes and other materials.
- Staff support from the Medicaid agency.
- Transportation assistance, child care, accessible meeting locations, training materials, and stipends for enrollee participants.
- Defined responsibilities, such as focus groups, community needs assessments, and enrollee satisfaction surveys outside of the EQR and CAHPS®.

HHS should also periodically review compliance with the state and MCO stakeholder provisions, as well as the MCAC requirements under current regulations, and initiate corrective action plans and other enforcement actions against states that fail to comply with federal requirements.

RECOMMENDATION: Amend § 438.70 as follows by designating the existing text as subsection (a), and adding subsections (b) – (h) as follows:

> ***(a)*** The State must ensure the views of beneficiaries, providers, and other stakeholders are solicited and addressed during the design, implementation, and oversight of a State's managed LTSS program. The composition of the stakeholder group and frequency of meetings must be sufficient to ensure meaningful stakeholder engagement.
> ***(b) Appointment – Members of the stakeholder group (hereinafter the "Committee") shall be appointed by the Governor or his or her designee. Appointment terms shall be on a "continuous and rotating" basis.***
> ***(c) Committee membership. The committee must include—***
> ***(1) At least 50 percent representation from enrollees or enrollee individual representatives, and should reflect the demographics of the population of individuals eligible for LTSS.***

[47] See 42 U.S.C. § 300ff–12.

(2) Members of enrollee advocacy groups.
(3) consumer organizations such as labor unions, cooperatives, consumer-sponsored prepaid group practice plans, and others; and
(3) State officials from agencies related to LTSS but that do not administer LTSS.
(4) Board-certified physicians and other representatives of the health and support services professions who are familiar with the needs of population groups using LTSS and with the resources available and required for their care;

(d) Committee participation. The Committee must have opportunity for participation in policy development, program administration, and oversight, including furthering the participation of beneficiary members in the agency program. The State must consult with the Committee in the development and review of:

(1) The comprehensive quality strategy required under § 431.504,
(2) The quality assessment and performance improvement programs under § 438.330,
(3) The development, implementation and evaluation of the quality rating system under § 438.334, and
(4) State monitoring requirements under § 438.66 and reports from the beneficiary support system required by § 438.71
(5) In addition, the Committee shall engage in additional activities to ensure that enrollees receive quality care, including conducting surveys of, and focus groups with, consumers about outcomes, experiences and quality of life.

(e) Committee staff assistance and financial help. The agency must provide the committee with—

(1) Staff assistance from the agency and independent technical assistance as needed to enable it to make effective recommendations; and
(2) Financial arrangements, if necessary, to make possible the participation of beneficiary members, including transportation assistance, child care, and stipends for enrollees.
(3) The agency is to provide for independent technical help, as needed to enable the Committee to make effective recommendations.

(f) Public deliberations - The Committee may not be chaired solely by an employee of the state.

(1) The meetings of the Committee, sub-committees, and workgroups shall be open to the public that is provided not less than two weeks in advance and which must be posted to the agency website. Meetings must be held in accessible locations.
(2) The records, reports, transcripts, minutes, agenda, membership list, training materials, by-laws or other documents which were made available to or prepared for or by the Committee shall be available for public inspection and copying at a single location and posted on the

state agency's website in a timely manner.
(3) Detailed minutes of each meeting of the Committee shall be kept. The accuracy of all minutes shall be certified to by the chair(s) of the Committee.
(4) This subparagraph does not apply to any disclosure of information of a personal nature that would constitute a clearly unwarranted invasion of personal privacy, including any disclosure of medical information or personnel matters.

(g) Review – Within 180 of the effective date of this provision, and at least once every three years thereafter, CMS shall conduct a review to determine state compliance with these requirements. States found deficient and that fail to implement a corrective action plan will be subject to a 1% reduction in FFP.
(h) The requirements of this subsection shall apply to § 431.12

§ 438.71 - Beneficiary support system

Medicaid managed care has proven to be a difficult system to navigate for many beneficiaries. Enrollees often encounter problems in connection with 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 plan 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. Such activities must be performed by knowledgeable professionals in a conflict-free manner that is accessible and meaningful for that individual and/or their caregivers. As much as we support having a BSS, however, we are concerned that as written, the BSS will not provide the services needed by enrollees and may raise in the enrollees a false expectation of assistance, which will likely increase enrollee dissatisfaction. We therefore urge that the BSS requirements be revised to ensure that the system will truly meet the needs of enrollees in Medicaid managed care, especially as it continues to evolve and may become more complex.

a. Inclusion of caregivers

As proposed, the BSS would only serve current and potential enrollees. We believe this is too limiting and suggest that caregivers be included because many beneficiaries have others helping them when making decisions regarding managed care selection or are seeking information to resolve a problem. This may be because they are ill and want help fighting treatment barriers, because they use supported decision making, or because they generally use help in their lives for such matters. In previous guidance regarding MLTSS and managed care, CMS included caregivers in the description of the

essential elements regarding beneficiary support. We agree with the inclusion of caregivers as many caregivers are not formal guardians but provide substantial support in decision making for beneficiaries. Therefore, we are recommending the addition of caregivers to the general requirement about whom the BSS serves. Broadening who the BSS can provide services to will help eliminate an incentive for guardianship or other forms of substituted decision making and falls in line with recent regulations about person-centered planning and the importance of the individual driving decisions.

b. Core minimum functions of a beneficiary support system

A BSS should have core minimum functions that provide the necessary support to enrollees and potential enrollees. We believe that the minimum functions of a BSS should provide the same or more services to the beneficiaries than it does for managed care entities or providers in that system. We believe that outreach is important, but is insufficient by itself and needs the additional components of training and education to help beneficiaries understand managed care and enrollee rights. Therefore, we recommend that training for beneficiaries be included as a function of the BSS. 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 and we therefore recommend training be extended to the beneficiaries directly.

We further recommend that the education and navigation assistance functions set forth in subsections (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 because they lack the case manager or similar services that may assist those receiving LTSS. 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. Being less restrictive about who the BSS may assist, even if the assistance is targeted based on needs identified by the BSS, would have an added benefit of ensuring that the state would be better informed about how managed care is functioning for all managed care beneficiaries and it would more fully serve the title of a BSS.

c. Role in grievances and appeals

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 with their plan 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 part F, including providing a chance to resolve the issue and ensuring that the grievance is recorded and thus 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, this information 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 the grievances 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 therefore recommend broadening the monitoring and reporting role of the BSS by requiring monitoring and reporting of program data to the state on all aspects of the program, not just LTSS.

d. *Conflict of interest and BSS entities*

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. We also agree that an entity that receives non-Medicaid funding to represent beneficiaries at hearings should, subject to approval by CMS, be able to provide choice counseling as an independent function. 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.

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 clearly do not have an interest in the managed care entity or the state's relationship with such an entity. 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.

RECOMMENDATION: Amend § 438.71 as follows:

(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 CMS, establish firewalls to provide choice counseling as an independent function and may provide the other functions of this section.

(i2) [Reserved]

(b) *Elements of the support system.*

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

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

(ii) ***provide*** train~~ing for~~ network providers as specified in paragraph (d) of this section***;***

(iii) assist~~ance for~~ 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.

~~(iv) Assistance for enrollees who use, or express a desire to receive, LTSS as specified in paragraph (e) of this section.~~

(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.~~

(c) *Choice counseling.*

(1) Choice counseling, as defined in § 438.2, must be provided to all potential enrollees and enrollees who disenroll from a MCO, PIHP, PAHP, PCCM or PCCM entity for reasons specified in §438.56(b) and(c).

(2) If an individual or entity provides choice counseling on the State's behalf under a memorandum of agreement or contract, it is considered an enrollment broker as defined in § 438.810(a) and must meet the independence and freedom from conflict of interest standards in §438.810(b)(1) and (2).

(d) *Training.* The beneficiary support system must provide training to MCOs, PIHPs, PAHPs, PCCMs, PCCM entities and network providers on community-based resources and supports that can be linked with covered benefits.

~~(e) Functions specific to LTSS activities. At a minimum, the beneficiary support system must provide the following support to enrollees who use, or express a desire to receive, LTSS:~~

~~(1) An access point for complaints and concerns about MCO, PIHP, PAHP, PCCM, and PCCM entity enrollment, access to covered services, and other related matters.~~

~~(2) 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.~~

~~(3) Assistance, 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.~~

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

~~(ii) [Reserved]~~

~~(4) Review and oversight of LTSS program data to provide guidance to the State Medicaid Agency on identification, remediation and resolution of systemic issues.~~

§ 438.72 - Language access and disability access (*proposed new section*).

Requirements to provide language access and accessibility for individuals with disabilities have existed since the 1960s. Yet we continue to hear ongoing problems from consumers who try to access these services. The Americans with Disabilities Act and Executive Order 13166 (combined with HHS' Office for Civil Rights' LEP Guidance) brought renewed attention to the issues people with disabilities and people who are limited English proficient, respectively, face. Unfortunately, however, we have not seen significant progress in managed care settings regarding the provision of needed services. In fact, in the managed care context, it seems that many managed care organizations do not understand that the requirements of the ADA, section 504 of the Rehabilitation Act, Title VI of the Civil Rights Act and section 1557 of the Affordable Care Act apply directly to them. So while we have also suggested specific requirements regarding contracting, we also strongly recommend that the rule governing Medicaid managed care regulations goes beyond general requirements and includes specific detailed requirements to create specific provisions that can be monitored and enforced by the state and enrollees.

While we appreciate the inclusion of specific language and disability access provisions in § 438.10 regarding information requirements, those requirements are limited in scope and do not apply more broadly when enrollees are accessing actual services. Thus, we recommend that HHS include specific regulatory requirements in the final rule to outline the expected services plans must provide to ensure language access and accessibility for individuals with disabilities.

Managed care enrollees may encounter a variety of issues with accessibility and language access, including:

- Lack of accessible communication. This includes print materials, call centers, customer service or care access lines, care coordinators, service providers, and grievance procedures.
- Few or no providers with accessible facilities and equipment or established language services procedures to provide reasonable accommodations, so that enrollees may have equal access to the services.
- Service networks that do not reflect the language and cultural makeup or accessibility needs of the service area. Without appropriate service providers, individuals either cannot access care or will be more unlikely to do so because the provider does not understand their needs.

- Use of friends, families, companions, and others as interpreters regardless of whether it is appropriate or if that individual is proficient in both languages (including relevant medical terminology) to provide effective communication.
- Lack of a well-publicized mechanism for an enrollee to request accommodations, translation, or interpreter services and managed care employees who are unaware or insufficiently trained regarding such a mechanism so as to direct enrollees to the process.

Due to the ongoing nature of problems people with disabilities and people with limited English proficiency experience in both enrolling in and accessing services in Medicaid managed care organizations, we recommend including the following language specifically in the rule.

RECOMMENDATION: Add new § 438.72

(a) General rule. A State that requires Medicaid beneficiaries to enroll in an MCO, PIHP, PAHP, or PCCM shall ensure that the MCO, PIHP, PAHP or PCCM complies with the requirements in subparagraph (b) regarding assistance for individuals who are LEP and subparagraph (c) ensuring access for individuals with disabilities.

(b) Standards for Ensuring Access to Individuals who are Limited English Proficient. The following standards shall apply to ensure that information provided to any potential enrollee or enrollee is culturally and linguistically appropriate to the needs of the population being served, including individuals who are LEP such that an MCO, PIHP, PAHP and PCCM must:

(1) Develop and maintain general knowledge about the racial, ethnic, and cultural groups in their service area, including each group's diverse cultural health beliefs and practices, preferred languages, health literacy, and other needs;

(2) Collect and maintain updated information to help understand the composition of the communities in the service area, including the primary languages spoken;

(3) In compliance with §438.10(c) and (f), provide enrollees and potential enrollees with information and assistance in the consumer's preferred language, at no cost to the enrollee or potential enrollee, including the provision of oral interpretation of non-English languages and the translation of written documents in non-English languages when necessary or when requested by the enrollee to ensure effective communication.

(i) Use of an enrollee's adult family or friends as oral interpreters can satisfy the requirement to provide linguistically appropriate services only when requested by the enrollee as the preferred alternative to an offer of other interpretive services and the MCO,

PIHP, PAHP or PCCM evaluates the competency of the family member to serve as an interpreter;

(ii) An accompanying adult may not be relied upon when there is reason to doubt the person's impartiality or effectiveness.

(iii) An adult or minor child may be relied upon to interpret or facilitate communication only when a qualified interpreter is not available in an emergency involving an imminent threat to the safety or welfare of an individual or the public.

(4) Provide oral and written notice to enrollees with LEP, in their preferred language, informing them of their right to receive language assistance services and how to obtain them;

(5) Provide staff ongoing education and training in culturally and linguistically appropriate service delivery; and

(6) Implement strategies to recruit, support, and promote a staff that is representative of the demographic characteristics, including primary languages spoken, of the communities in their service area.

(c) Standards ensuring access by persons with disabilities. The following standards will apply to ensure that information provided to any potential enrollee or enrollee is culturally and linguistically appropriate to the needs of the population being served, including individuals with disabilities. An MCO, PIHP, PAHP or PCCM must:

(1) Ensure that any consumer education materials, Web sites, or other tools utilized for consumer assistance purposes, are accessible to people with disabilities, including those with sensory impairments, such as visual or hearing impairments, and those with mental illness, addiction, and physical, intellectual, and developmental disabilities;

(2) Ensure that notices are provided in alternative formats or communicated using auxiliary aids and services when needed to ensure effective communication of information with individuals with disabilities;

(3) Provide assistance to enrollees or potential enrollees in a location and in a manner that is physically and otherwise accessible to individuals with disabilities;

(4) Provide effective communication to covered companions with communication disabilities;

(5) Ensure that authorized representatives are permitted to assist an individual with a disability to make informed decisions;

(6) Acquire sufficient knowledge to refer people with disabilities to local, State, and federal long term services and supports programs when appropriate;

(7) Be able to work with all individuals regardless of age, disability, or culture, and seek advice or experts when needed; and

(8) Provide auxiliary aids and services for individuals with disabilities, at no cost, when necessary or when requested by the enrollee or potential enrollee to ensure effective communication.

(i) Use of an enrollee's adult family or friends as can satisfy the requirement to provide auxiliary aids and services only when requested by the enrollee or potential enrollee as the preferred alternative to an offer of other auxiliary aids and services, the accompanying adult agrees, and reliance on the accompanying adult is appropriate under the circumstances.

(ii) An accompanying adult may not be relied upon when there is reason to doubt the person's impartiality or effectiveness.

(iii) An adult or minor child may be relied upon to interpret or facilitate communication only when a qualified interpreter is not available in an emergency involving an imminent threat to the safety or welfare of an individual or the public.

(d) Monitoring. Any MCO, PIHP, PAHP or PCCM during the exercise of its authority will monitor compliance with the standards in this section.

If HHS adopts these recommendations, we would suggest including the definitions of competent healthcare interpreters and translation that we recommended in § 438.10 in this section. In that case, HHS could include a cross-reference in § 438.10 to this new section so that all the relevant language re: definitions for language access are in one provision.

§ 438.74 - State oversight of the minimum MLR requirement

a. § 438.74(a) State reporting requirement

We commend HHS for proposing rules regarding state oversight of minimum MLR requirements, including repayment of federal share of remittances.

Although we understand that HHS may generally prefer to review state MLR report *summaries* (and that such summaries may generally be more helpful to consumers as well), t we believe that HHS should also collect the state MLR *reports* from plans. This is particularly true in the early years of MLR reporting when HHS may have numerous technical issues with how data is calculated and reported, and HHS will face challenges ensuring consistent reporting within and between states.

We also recommend that HHS require public reporting of the MLR reports *and* report summaries submitted by states to HHS. First, they should be posted on the state Web site. We further recommend requiring that reports and summaries be posted and available on an HHS website allowing consumers, plans, and others to see statewide MLR reports and summaries.

RECOMMENDATION: Amend § 438.74(a)(1) 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 must be posted on the state's Web site established pursuant to § 438.10(c)(30 [state website – see 438.10] The reports and summaries must also be made publically available by HHS, including by posting on an internet website.***

NATIONAL HEALTH LAW PROGRAM

SUBPART C

§ 438.100 - Enrollee rights.

a. *Section generally-title and purpose clarification*

Despite its title, § 438.100 does not contain many individual rights provided by these regulations, such as the right to be free from discrimination, to file grievances and appeals, to disenroll in certain circumstances, or to access emergency and out-of-network services. Rather, it mostly reflects rights that are not explicitly set forth elsewhere in the regulations. We believe that the title of this section is misleading because the section does not provide a complete list of all enrollee rights." Thus, the title could cause confusion and lead to overly limited and inaccurate information about and education on enrollee rights . In addition to these suggestions, we also offer support for the change to (a)(2) to more clearly set forth the state's obligation to ensure that each managed care entity and its employees and providers comply with laws pertaining to enrollee rights.

b. Person-centered health care decisions for all

The right to participate in one's own healthcare is a fundamental right in any healthcare situation, given the personal nature of such decisions. This is true regardless of whether or not the person has a guardian or legal representative. In some cases of substituted decision making, the representative may not have the same cultural considerations or beliefs as the individual for whom they are making decisions. It is therefore important that the individual drive their own healthcare decisions. In order to be better aligned with the current movement to greater recognition of person-centered care and self-determination, we strongly believe there should be recognition in the enrollee rights section that healthcare decisions should be driven by the individual to the extent possible. This concept is already reflected elsewhere in Medicaid, such as in the home and community based services regulations, and should be reflected in these regulations. This change would also help meet CMS's stated goal of modernizing the Medicaid managed care regulations to reflect current norms.

RECOMMENDATION: Amend § 438.100 by changing the section heading to "Additional enrollee rights" and revise the language as follows to remove references to rights set forth elsewhere, and add:

(a) General rule. The State must ensure that:
(1) Each MCO, PIHP, PAHP, PCCM and PCCM entity has written policies regarding the ***additional*** enrollee rights specified in ***paragraph (b)(1) of*** this section; and
….
(b) Specific rights.

~~(1) Basic requirement. The State must ensure that each managed care enrollee is guaranteed the rights as specified in paragraphs (b)(2) and (b)(3) of this section.~~

(~~2~~***1***) An enrollee of an MCO, PIHP, PAHP, PCCM or PCCM entity has the following rights:

The right to—

~~(i) Receive information in accordance with § 438.10.~~

…

~~(iv)~~ ***(iii)*** Participate in decisions regarding his or her health care, including the right to refuse treatment. ***If an enrollee has a guardian or legal representative, the health care decision should be driven by the individual.***

~~(3) An enrollee of an MCO, PIHP, or PAHP has the right to be furnished health care services in accordance with §§ 438.206 through 438.210.~~

a. Compliance with other laws—nondiscrimination provision

Where the regulations discuss nondiscrimination and the applicable statutes, this listing should be inclusive of all current Federal laws. The language in subsection (d) should be similar to that proposed at § 438.3(f)(1) and § 457.1201(e)(1). Therefore, we recommend adding to subsection (d) references to § 1557 of the Patient Protection and Affordable Care Act, Title IX of the Education Amendments of 1972, and updating the language for the Americans with Disabilities Act.

RECOMMENDATION: Amend § 438.100(d) as follows:

(d) Compliance with other Federal and State laws. The State must ensure that each MCO, PIHP, PAHP, PCCM and PCCM entity complies with any other applicable Federal and State laws ***and regulations*** ~~(~~including~~:~~ Title VI of the Civil Rights Act of 1964 ~~as implemented by regulations at 45 CFR part 80~~; ***Title IX of the Education Amendments of 1972 (regarding education programs and activities);*** the Age Discrimination Act of 1975 ~~as implemented by regulations at 45 CFR part 91~~; the Rehabilitation Act of 1973; ~~and~~ Titles II and III of the Americans with Disabilities Act ***of 1990 as amended~~);~~ and section 1557 of the Patient Protection and Affordable Care Act***.

§ 438.102 - Provider-enrollee communications

a. Information about excluded counseling or referral services

When a managed care entity refuses to reimburse or provide coverage for a counseling or referral service for moral or religious reasons, enrollees may have trouble accessing these services in a timely manner. As noted above, we are very pleased that HHS has amended § 438.10(g)(2)(ii)(B) to require that a managed care entity inform enrollees how they can obtain information from the state about how to access a counseling or

referral service that the entity does not cover. This requirement will help to ensure that individuals have meaningful and timely access to all services available under the state plan. As proposed, § 438.102(b)(2) incorporates this requirement by reference. However, we are concerned that the text of that provision could be somewhat misleading, as it only explicitly states that MCOs, PIHPs, and PAHPs do not have to inform enrollees and potential enrollees how and where to obtain excluded counseling or referral services.

In addition, as discussed above, we are concerned that § 438.10(e)(2)(v)(C) does not require that a managed care entity provide potential enrollees with information about how they can obtain information from the state about how to access a counseling or referral service that the entity does not cover. This omission is reflected in § 438.102(b)(2), as proposed. Accordingly, we urge HHS to amend § 438.102(b)(2) to explicitly state that MCOs, PIHPs, and PAHPs must inform enrollees and potential enrollees how they can obtain information from the state about how to access counseling or referral services that their plan refuses to cover for moral or religious reasons.

RECOMMENDATION: Amend § 438.102(b)(2) as follows:

> (2): "As specified in 438.10***(e)(2)(v)(C) and 438.10***(g)(2)(ii)(A) and (B), the information that MCOs, PIHPs, and PAHPs must furnish to enrollees and potential enrollees does not include how and where to obtain the service excluded under paragraph (a)(2) of this section, ***but must include how to obtain information from the State about how to access the service***."

§ 438.104 - Marketing activities

QHPs available through the Marketplaces are prohibited from engaging in marketing practices that discourage persons with significant health needs from enrolling.[48] HHS should apply similar restrictions to Medicaid managed care plans. HHS should strengthen regulations so that plans cannot engage in adverse selection by reviewing all marketing materials for potentially discriminatory effect.

RECOMMENDATION: Amend § 438.104(c) as follows:

> (c) State agency review.
>
> (1) In reviewing the marketing materials submitted by the entity, the State must consult with 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.***
>
> ***(2) The State must review all marketing materials and informing practices for accuracy of information, language, reading level,***

[48] 42 U.S.C. § 18031(c)(1)(a).

comprehensibility, cultural sensitivity and diversity. Marketing materials must conform to the requirements in §438.10.
(3) The State must review all marketing materials and informing practices to ensure that the MCO, PHIP, PAHP, or PCCM entity does not target or avoid populations based on their perceived health status, cost or for other discriminatory reasons.
(4) The State must review all marketing materials for information that would be misleading in context to a person not possessing special knowledge regarding health care coverage as to the benefits, costs, provider networks or availability or services provided by the plan.

§ 438.106 - Liability for payment

HHS has consistently confirmed that individuals enrolled in Medicaid are entitled to freedom of choice of family planning provider and must be free of coercion to choose their method of contraception. Given these protections, when an individual seeks a provider of family planning services outside of the managed care network and chooses a method of contraception that their managed care plan normally does not cover, the enrollee should not be charged for those services. The managed care plan must pay the out-of-network provider for the services. We recommend that HHS add a new subsection (d) to clarify that the enrollee cannot be charged for family planning services and supplies and family planning-related services that are covered by the State plan when obtained out-of-network, even if a specific service or supply is not covered by the enrollee's managed care plan.

RECOMMENDATION: Add subsection (d):

(d) Family planning services and supplies and family planning-related services covered by the State plan and obtained out-of-network.

§ 438.108 - Cost sharing

We support the clear requirement that managed care contracts under Part 438 must comply with all Medicaid cost sharing regulations. However, it appears that the proposed regulation includes an outdated cross-reference. We believe this was simply a drafting error.

RECOMMENDATION: Revise § 438.108 to update the cross-reference to the current Medicaid cost sharing citations as follows:

> The contract must provide that any cost sharing imposed on Medicaid enrollees is in accordance with §§ 447.50 through ~~447.82~~ ***447.57*** of this chapter.

§ 438.110 - Member advisory committee.

We strongly support HHS' proposal to require states to develop plan-level LTSS stakeholder advisory committees, recognizing that enrollees and other stakeholders can play a critical role in the success of a MLTSS program.
However, we strongly disagree with HHS' proposal to allow state and plans flexibility in the design and implementation of LTSS stakeholder groups. The proposed rule is too broad and too vague to allow for meaningful and sustained stakeholder engagement. (Please see NHeLP's comments on § 438.70 above).

State agencies and managed care plans have a poor track record engaging consumers and other stakeholders in program in planning, implementation, and oversight. Accordingly, we recommend that HHS establish detailed requirements for state LTSS stakeholder groups, with clear requirements for membership, operations, responsibilities, and transparency, aligning requirements for the LTSS stakeholder groups with the state-established MCAC and LTSS stakeholder group.

In addition, we recommend omitting the reference to coverage through a risk contract. The preamble suggests that this requirement is important for contracts that include LTSS. 80 Fed. Reg. at 31144. Given that PCCM entities are evolving and may include coverage of LTSS as part of their contracts, they should not be exempted from this requirement.

RECOMMENDATION: Amend § 438.110 as follows:

(a) *General rule.* When LTSS are covered under a risk contract between a State and an MCO, PIHP, or PAHP the contract must provide that each MCO, PIHP***,*** ~~or~~ PAHP***,*** or PCCM entity establish and maintain a member advisory committee.
(b) *Committee composition.* The committee required in paragraph (a) of this section must include:
(1) ***At least 50 percent representation from enrollees, enrollee representatives, and caregivers who are*** ~~a~~ reasonably representative sample of the LTSS populations covered under the contract with the MCO, PIHP, ~~or~~ PAHP, ***or PCCM entity***,
(2) Members of legal services providers, consumers' groups, and consumer organizations such as labor unions, cooperatives, coalitions, and others;(3) The MCO, PIHP, PAHP's, or PCCM entity's medical director or director of LTSS services who is responsible for services authorization and utilization management.
(c) Committee participation. The Committee must have opportunity for participation in policy development, program administration, and oversight, including furthering the participation of beneficiary members in the agency program. The State must consult with the Committee in the development and review of:

(1) The comprehensive quality strategy required under § 431.504,
(2) The quality assessment and performance improvement programs under § 438.330,
(3) The development, implementation and evaluation of the quality rating system under § 438.334, and
(4) State monitoring requirements under § 438.66.
(5) In addition, the Committee shall engage in additional activities to ensure that enrollees receive quality care, including conducting surveys of, and focus groups with, consumers about outcomes, experiences and quality of life.

(d) Committee staff assistance and financial help. The MCO, PIHP, PAHP, or PCCM entity must provide the committee with—
(1) Staff assistance from the agency and independent technical assistance as needed to enable it to make effective recommendations; and
(2) Financial arrangements, if necessary, to make possible the participation of beneficiary members, including transportation assistance, child care, and stipends for enrollees.
(3) The MCO, PIHP, PAHP, or PCCM entity is to provide for independent technical help, as needed to enable the Committee to make effective recommendations.

(e) Public deliberations. The Committee may not be chaired solely by an employee of the MCO, PIHP, PAHP, or PCCM entity.
(1) The meetings of the Committee, sub-committees, and workgroups shall be open to the public and shall be held only after adequate notice to the public that is provided not less than two weeks in advance and is posted to the MCO, PIHP, or PAHP website. Meetings must be held in accessible locations.
(2) The records, reports, transcripts, minutes, agenda, membership list, training materials, by-laws or other documents which were made available to or prepared for or by the Committee shall be available for public inspection and copying at a single location and posted on the MCO, PIHP, PAHP, or PCCM entity website in a timely manner.
(3) Detailed minutes of each meeting of the Committee shall be kept. The accuracy of all minutes shall be certified to by the chair(s) of the Committee.
(4) This subparagraph does not apply to any disclosure of information of a personal nature that would constitute a clearly unwarranted invasion of personal privacy, including any disclosure of medical information or personnel matters.

(f) Review. Within 180 of the effective date of this provision, and at least once every three years thereafter, the State shall conduct a review to determine compliance with these requirements. MCO, PIHP, PAHP, or PCCM entity found deficient and that fail to implement a corrective action plan will be subject to sanctions described in subpart I.

NATIONAL HEALTH LAW PROGRAM

§ 438.114 - Emergency and post stabilization services

We concur with the technical corrections that HHS is proposing to this section. We agree that PCCMs should not bear any financial responsibility for emergency and post stabilization services. In addition, we appreciate the clarification regarding payment guidelines for emergency and post stabilization care to specify that these services should be paid according to federal and state Medicaid payment rates, not Medicare rates. We believe that these corrections will provide additional clarity to ensure that consumers receive appropriate emergency and post stabilization care and are not billed for these services.

We are aware of situations where consumers are forced to seek care in an emergency department because their managed care entity is not able to offer the needed service in a timely or accessible manner. While we appreciate that the proposed regulations make several changes aimed at ensuring that such shortages are not prevalent, we do not think that all plans will be able to ensure that all covered services are available in a timely and accessible manner all of the time. Thus, we anticipate that there will be continue to be some situations, however rare, when a consumer has no option to obtain needed care other than to seek it in an emergency setting. For example, in many regions, a consumer with a severe migraine might ordinarily be able to seek treatment from her primary care provider or an urgent care center during normal business hours, but her plan may not have any provider in a non-emergent setting who is able to provide care if a migraine comes on during evening or weekend hours. The consumer may not be able to wait until business hours to get treatment. We urge HHS to clarify that consumers should not be penalized for seeking care in an emergency room when they have been unable to obtain it from their plan in another setting.

RECOMMENDATION: Amend by adding the subsection (C) as follows:

> ***§ 438.114(c)(1)(ii)(C) An enrollee has not been able to obtain non-emergency services from the MCO, PIHP, PAHP, PCCM, or PCCM entity in a timely or accessible manner.***

NATIONAL HEALTH LAW PROGRAM

SUBPART D

§ 438.206 - Availability of services

We appreciate that HHS is proposing to keep the current framework of service accessibility in § 438.206. In conjunction with the new proposed § 438.68, this section will help to meet HHS's goal of ensuring that that Medicaid managed care enrollees can access the services to which they are entitled. As described in more detail below, we recommend, that HHS add language to this section to further strengthen § 438.206 to fully meet HHS's goal of ensuring access.

a. § 438.206(b)(1) – Provider network requirements

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's 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, by referring to the definition of services we propose be added to § 438.2. This language will 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.

We also suggest that HHS specifically note in this section that in maintaining and monitoring their networks, plans must account for the network adequacy requirements set forth at § 438.68(c). In § 438.68(c), HHS has set forth specific considerations for states and plans to consider in evaluating whether a provider network will provide adequate access to covered services—many of which are criteria for consideration in the current version of this section. We believe it is consistent with HHS's intent that in maintaining and monitoring their networks, plans should account for those same considerations.

RECOMMENDATION: Amend § 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, including ***as defined in § 438.2 of this chapter, 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.

b. § 438.206(b)(2) – Access to women's health specialists

We commend HHS for continuing to require plans to provide direct access to women's health specialists. We ask HSS to make two clarifications to this section. First, we suggest that HHS specify that adolescent female enrollees should be provided with direct access to women's health specialists. We are aware of plans that have interpreted the phrase "women's health specialist" to exclude such access for enrollees under age 18, even when those enrollees need the services provided by women's health specialists such as diagnosis and treatment for irregular or painful menstrual cycles, family planning counselling, treatment for premenstrual syndrome, screening and treatment for sexually transmitted infections, and prenatal care. We do not believe HHS's intends adolescents to be excluded from the group of female enrollees who can have direct access to a specialist for these services, and we suggest that it say so explicitly to avoid any further confusion.

Second, we ask that HSS remove the qualifying phrase "routine and preventive" from the phrase "women's health care services." We are concerned that by limiting direct access to routine and preventive services will encourage plans to place barriers that will impede enrollee's access to women's health specialists. Female enrollees require access to women's health specialists for a wide range of women's health services that may not neatly fit into a definition of "routine and preventive" care, including counselling and treatment for irregular or painful menstrual cycles, abortions, follow-up care after an irregular pap test or mammogram, colposcopies, diagnosis and treatment for premenstrual syndrome, diagnosis and treatment of perinatal or postpartum depression, treatment for symptoms associated with menopause, and treatment of vaginal and urinary tract infections and sexually transmitted diseases. We strongly suggest that HHS require direct access for all women's health care services, not only those that can be classified as "routine and preventive."

RECOMMENDATION: Amend § 438.206(b)(2) as follows:

> § 438.206(b)(2) Provides female enrollees***, including adolescents,*** with direct access to a women's health specialist within the provider network for covered care necessary to provide women's ~~routine and preventive~~ health care services. This is in addition to the enrollee's designated source of primary care if that source is not a women's health specialist.

c. § 438.206(b)(4)-(5) – Access to out-of-network providers

We appreciate that HHS will continue to require plans to allow enrollees to obtain care from an out-of-network provider when necessary services are not available from the plan's network. We share HHS's conviction that the Medicaid Act requires enrollee's to have access to all covered services, which requires managed care enrollees to have a mechanism to obtain needed care from an out-of-network provider when an appropriate provider is not available in the plan's network. We suggest that HHS add more specific language to ensure that § 438.206(b)(4) will achieve this aim.

In particular, we suggest that HHS add three cross-references to other provisions related to out-of-network access in order to improve clarity by keeping all of the out-of-network provisions in one place. Adding these references to § 438.206(b)(4) is particularly important, because we believe that the provisions of § 438.206(b)(5) related to payment of out-of-network providers and cost-sharing for enrollees should apply in these scenarios. Listing them in § 438.206(b)(4) will make clear that § 438.206(b)(5) applies to each situation where enrollees may seek care from an out-of-network provider. We recommend that HHS add a reference to the transition of care provisions of § 438.62(b) to this section, since those provisions will now permit managed care enrollees to see out-of-network providers in certain circumstances. We also suggest that HHS explicitly affirm in this section that enrollees of childbearing age have a right to seek family planning services from out-of-network providers pursuant to the Medicaid Act's freedom of choice provisions, and to make clear that enrollees are entitled to all family planning services and supplies and family-planning related services that are covered under the State plan regardless of whether they are covered by the MCO, PIHP, PAHP, PCCM, or PCCM entity.

Finally, we suggest that HHS in this section remind plans of their obligation to permit enrollees to receive emergency and post stabilization care from out-of-network providers as required by § 438.114, including in situations where an enrollee seeks emergency care after not being able to obtain non-emergency services from the MCO, PIHP, PAHP, PCCM, or PCCM entity in a timely or accessible manner.

Further, we suggest moving some of the specific language that HHS proposed to add to § 438.52(b) regarding out-of-network access instead to this section. We believe that the proposed out-of-network exceptions are appropriate not only for enrollees in rural areas with limited plan choice, but for all enrollees, since the specified scenarios may occur in urban or suburban communities, or in rural areas where enrollees have a choice of health plans. We recommend that HHS specify that enrollees have a right to seek care out-of-network when a needed provider type, in terms of the provider's training, experience, or specialization, is not available in-network. For example, there are cases, even in major urban areas such as Los Angeles and D.C., where a Medicaid managed care plan does not contract with a very rare subspecialist, such as a pediatric endocrinologist, or orthopedic surgeon. There are other situations where an enrollee requires not just any specialist, but one with a particular background of training and expertise. For example, enrollees who are dually infected with hepatitis C and HIV are best treated by providers with experience and training in treating both conditions; an infectious disease specialist who is unfamiliar with hepatitis C or heptologist who does not ordinarily treat individuals with HIV may not be able to appropriately treat a dually infected enrollee. When an enrollee needs care from a provider with a particular specialization, training, or expertise, and none is available in her plan's network, she must be permitted to go out-of-network.

In addition, we strongly urge HHS to include two specific situations that warrant out-of-network access, currently set forth in proposed § 438.52(b), in this section instead. First,

HHS should explicitly affirm in this section that enrollees may seek care from an out-of-network provider when the only plan, provider, or facility available refuses to provide a needed service due to a moral or religious objection. Under federal and state laws, providers and plans have various rights to refuse to provide services to which they have a moral or religious objection, such as family planning, gender transition services, and abortions. When those services are covered by plan's contract, the enrollee must be allowed to seek services out-of-network if the plan or all of its in-network facilities or providers refuse to provide the needed service. Second, HHS should also affirm in this section enrollees may seek services from an out-of-network provider when the enrollee needs related services that would subject the enrollee to unnecessary risk if received separately, and not all of the related services are available within the network. For example, enrollees who require a cesarean section and a tubal ligation benefit from having both procedures performed at the same time, rather than undergoing two separate surgeries with their attendant risks, and convalescing through two separate recovery times. We do not believe that these situations only occur in rural areas, and thus these protections should be extended to all Medicaid managed care enrollees, regardless of geography or the number of plan options they have.

Finally, we recommend that HHS include a "catch-all" provision that specifically permits states to identify other circumstances where enrollees must be allowed by their plans to seek care out-of-network. For example, we are aware of some states, including Maryland, allow enrollees under 21 to obtain care out-of-network access for certain EPSDT services. Other states, such as California, have extended the concept of "freedom of choice" to allow enrollees to seek care from out-of-network providers for a broad range of reproductive health services, beyond family planning services. We urge HHS to make clear in this section that states have the flexibility to identify situations that warrant out-of-network access beyond those enumerated in the section.

We commend HHS for continuing to ensure in § 438.206(b)(5) that, in all situations where enrollees are entitled to seek care from an out-of-network provider, enrollees not be subjected to any additional cost-sharing. We also strongly support the provisions of this section that require out-of-network providers and Medicaid plans to coordinate payment for services that enrollees receive on an out-of-network basis without involving the enrollee in those payment conversations. Too often, even when a plan authorizes an enrollee to seek treatment from an out-of-network provider, the enrollee becomes embroiled in a payment dispute between plan and provider. We believe that the provisions of § 438.206(b)(5) serve as an important protection against enrollees being subjected to billing disputes or balance billing. We do not suggest any changes to this section.

RECOMMENDATION: Amend § 438.206(b)(4) as follows:

> ***The MCO, PIHP or PAHP must allow an enrollee to receive care from an out-of-network provider i~~I~~f:***

(i)T~~t~~he provider network is unable to provide necessary services, covered under the contract, ***or type of provider (in terms of training, experience, and specialization)*** to a particular enrollee, the MCO, PIHP, or PAHP must adequately and timely cover these services out of network for the enrollee, for as long as the MCO, PIHP, or PAHP's provider network is unable to provide them~~.~~***, including situations when:***

(A) The only plan or provider available to the beneficiary does not, because of moral or religious objections, provide the service the enrollee seeks.

(B) The enrollee's primary care provider or other provider determines that the enrollee needs related services that would subject the enrollee to unnecessary risk if received separately (for example, a cesarean section and a tubal ligation) and not all of the related services are available within the network.

(ii)The enrollee is eligible to see the provider pursuant to the state's transition of care policy as described in § 438.62(b) of this chapter.

(iii) The enrollee is seeking family planning services described in § 1905(a)(4)(C)of the Act, consistent with § 1902(a)(23) of the Act, in which case the enrollee is entitled to all family planning services and supplies and family planning-related services covered under the State plan without cost-sharing whether or not the service or supply is covered by the MCO, PIHP, PAHP, PCCM, or PCCM entity.

(iv)The enrollee requires emergency or post stabilization services as described in § 438.114 of this chapter, including situations where enrollees seeks emergency care because they have not been able to obtain non-emergency services from the MCO, PIHP, PAHP, PCCM, or PCCM entity in a timely or accessible manner.

(v)The State determines that other circumstances warrant out-of-network treatment.

d. § 438.206(c)(1) – Timely access to care

We appreciate that HHS will continue to require plans to meet standards for timely access to care. As described in more detail in our comments to § 438.68 above, we suggest that HHS require states to ensure that contracted plans meet minimum quantitative standards for timely access. Thus, we suggest that this section reference those specific standards, which we have proposed to place in § 438.68.

In addition, we encourage HHS to add more detail to explain how plans should monitor their providers to ensure compliance with timely access. We recommend adding language to § 438.206(c)(1)(iv) to ensure that plans use direct testing methods to ensure that their networks provide timely access. We also recommend adding language to require plans to conduct such testing at least annually, and to report on the results, and any corrective action taken, to the state. We believe that these recommendations are consistent with those of the Office of Inspector General, which last year

recommended that HHS require states and plans to implement more robust monitoring of access to care, including using direct testing methods.[49] These methods could include enrollee or provider surveys, audits of appointment requests and encounter data, or secret shopper efforts. For example, California's Department of Managed Health Care, pursuant to a new statute, began this year requiring its licensed plans (including licensed Medicaid plans) to either survey their providers or audit their call records and encounter data.[50] We believe that adding a more robust requirement of the plans' internal monitoring complements the new requirements with respect to the state in § 438.207, described in more detail below.

RECOMMENDATION: Amend § 438.206(c)(1) as follows:

> § 438.206(c)(1) *Timely access*. Each MCO, PIHP, and PAHP must do the following:
> (i) Meet and require its network providers to meet State standards for timely access to care and services ***established in accordance with § 438.68(b)(3) of this chapter***, taking into account the urgency of the need for services.
> (ii) Ensure that the network providers offer hours of operation that are no less than the hours of operation offered to commercial enrollees or comparable to Medicaid fee-for-service, if the provider serves only Medicaid enrollees.
> (iii) Make services included in the contract available 24 hours a day, 7 days a week, when medically necessary.
> (iv) Establish mechanisms to ensure compliance by providers***, including direct testing of compliance through enrollee or provider surveys, audits of encounter data, secret shopper efforts, or similar methods.***
> (v) Monitor providers regularly***, no less than once per year,*** to determine compliance***, and report the results of these monitoring efforts to the state, as required by § 438.207 of this subpart***.
> (vi) Take corrective action if there is a failure to comply***, and report any corrective action taken to the state, as required by § 438.207 of this subpart***.

e. § 438.206(c)(2) – Cultural competence and language access

We greatly appreciate HHS's additions to this section to clarify the scope of cultural competency. We especially commend HHS's extending the requirement in § 438.206(c)(2) of plans to participate in cultural competency efforts to individuals with disabilities, and to all regardless of gender, sexual orientation or gender identity. We

[49] MURRIN, *supra* note 40 at 19.
[50] Cal. Health & Safety Code §§ 1367.03, 1367.035. *See also* Cal. Dept. of Managed Health Care, Submit Health Plan Filings and Reporting: Timely Access Report, http://www.dmhc.ca.gov/LicensingReporting/SubmitHealthPlanFilings.aspx#timely (last visited Jun. 26, 2015).

believe that these provisions will go a long way toward ensuring that female enrollees and LGBT enrollees receive culturally competent care.

We recommend adding language to this section to clarify that plans must provide language access services to all LEP enrollees, and that the plans must pay for the costs of such services. We are concerned that too often, funding for translation and interpretation services is not built into plan and provider contracts, which gives both the plans and the providers a disincentive from providing them. We believe that by specifying that plans have the ultimate responsibility for paying for these services, HHS can better ensure that they are regularly provided when needed.

RECOMMENDATION: Amend § 438.206(c)(2) as follows:

> *Access and cultural considerations*. Each MCO, PIHP, and PAHP participates in the State's efforts to promote the delivery of services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds, disabilities, and regardless of gender, sexual orientation or gender identity. ***Each MCO, PIHP and PAHP must ensure that services related to language access are provided to all potential enrollees and enrollees who are LEP.***

f. § 438.206(c)(2) – Disability access

We commend the addition of this section to clarify that Medicaid plans are responsible for providing access to enrollees with disabilities. As more Medicaid managed care programs enroll populations with disabilities and chronic health care needs, these protections are a vitally important component of ensuring access to care. We are especially heartened by HHS's decision to explicitly call out plans' responsibility for ensuring access, accommodations, and appropriate equipment for enrollees with both physical and mental disabilities. Similar to our comments above, we recommend that HHS add language to this section to clarify that plans, and not their providers, bear the ultimate financial responsibility for compliance with this section. This language will avoid confusion or shirking of responsibilities that could ultimately leave enrollees without critical access to care.

RECOMMENDATION: Amend § 438.206(c)(3) as follows:

> *Accessibility considerations.* Each MCO, PIHP, and PAHP must ensure that network providers provide physical access, accommodations, and accessible equipment for Medicaid enrollees with physical or mental disabilities. ***Each MCO, PIHP and PAHP must ensure that services related to disability access are provided to all potential enrollees and enrollees who have 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.[51] 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 greater detail below.

a. § 438.207(a) – Basic provisions

We commend CMS for continuing to require States to ensure that their contracted Medicaid plans provide assurances to the state regarding the adequacy of their networks. We suggest adding a specific reference to the network adequacy standards in new proposed § 438.68 in this section, to clarify that the assurances required by this section extend to the requirements of § 438.68.

RECOMMENDATION: Amend § 438.207(a) as follows:

> (a) *Basic rule.* The State must ensure, through its contracts, that each MCO, PIHP, and PAHP gives assurances to the State and provides supporting documentation that demonstrates that it has the capacity to serve the expected enrollment in its service area in accordance with the State's standards for access to care under this subpart ***and § 438.68 of this chapter***.

b. § 438.207(b)(1) – Documentation that network is sufficient to provide access to covered services

We appreciate that this section implements the requires of § 1932(b)(5)(A) of the Act to ensure that managed care plans provide the states with appropriate documentation to demonstrate that its network provides sufficient access to the types of services needed by enrollees. To achieve this goal, we recommend adding specificity about the nature of the documentation required. We suggest that HHS require states to collect from each MCO, PIHP, and PAHP, a complete provider directory, and review it for compliance with access requirements as described below. In particular, we urge HHS to ensure that

[51] *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.

states review these listings to ensure compliance with language and disability access requirements.

We also urge HHS to require states to closely review these directories to ensure that enrollee's access to care is not hampered by exclusive contracts with providers who refuse to provide certain health services pursuant to a moral or religious objection. We are aware of Medicaid managed care enrollees who have been denied access to contraception, miscarriage management, hormone therapy for gender dysphoria, HIV treatment, treatment for ectopic pregnancies, and a range of other services as a result of state or federal provider refusal laws. Where providers have a legal right to refuse to provide a covered service, the state and the plan must ensure that the plan's network will provide sufficient access to those covered services that providers may refuse to provide. We have suggested specific language below.

We further recommend that HHS require states to review plans' directories with respect to the provider types and ratios set forth in § 438.68(b). We also suggest that HHS require states to review the directories to ensure that plans contract with a sufficient number of emergency and urgent care providers. Finally, we suggest that HHS provide a non-exhaustive list of other providers who serve the Medicaid population, so that states have additional guidance when they review plans' provider directories for compliance.

RECOMMENDATION: Amend § 438.207(b)(1) as follows:

> (1) Offers an appropriate range of preventive, primary care, specialty services, and LTSS that is adequate for the anticipated number of enrollees for the service area.
>
> ***(i)The MCO, PIHP, or PAHP shall provide the state with a copy of its most current provider directory as set forth in § 438.10(h) of this chapter, which will demonstrate that its network includes a sufficient number of:***
>
> ***(A) Health care professionals who are able to communicate with limited English proficient enrollees in their preferred language in compliance with § 438.10;***
>
> ***(B) Health care professionals and facilities that ensure physical access, reasonable accommodations, culturally competent communications, and accessible equipment f***or ***enrollees with physical or mental disabilities in compliance with § 438.10;***
>
> ***(C) Health care professionals who provide a full range of covered services including high risk pregnancy care, family planning services and supplies, treatment for HIV and AIDS, gender transition services, and abortion. If an MCO, PIHP, or PAHP contracts with institutions or individual providers who***

refuse to provide a full range of health services, the MCO, PIHP, or PAHP must also demonstrate that it:

(I) Contracts with at least one institutional provider and one professional provider within the same geographic area that provides covered services in-network providers refuse to provide;

(II) If there is no provider in the geographic area that offers the covered services, contracts with additional providers in nearby regions and provide transportation services; and

(III) Ensures a protocol is in place to allow enrollees to obtain covered services when a primary care provider refuses or is unable to make a referral to needed services.

(D) The providers of services listed in § 438.68(b) of this chapter;

(E) Providers of ambulance services, emergency and urgently needed services, and post-stabilization care services coverage in accordance with § 438.114 of this chapter; and

(F) Other providers that serve the Medicaid populations, such as Ryan White HIV/AIDS Program Providers, Freestanding Birth Centers, STD Clinics, TB Clinics, Hemophilia Treatment Centers, Black Lung Clinics, and Community Mental Health Centers.

c. *§ 438.207(b)(2) – Documentation that network contains a sufficient mix and geographic distribution of providers*

We support HHS' decision to implement the requires of § 1932(b)(5)(B). Again, we suggest that HHS add more specific requirements to this section to achieve this goal. We recommend that HHS require states to use two approaches to monitoring the mix and distribution of providers. First, we suggest that HHS require states to assess compliance with the geographic access standards in § 438.68 by collecting both narrative descriptions and mapping of provider locations, as described in detail below. By requiring states to specifically review the locations of provider types on a map, HHS can ensure that states are closely monitoring the extent to which their contracted plans are meeting the geographic access requirements set forth in § 438.68, and readily identifying areas where corrective action is required to cure shortages. If HHS declines to implement our recommended language in this section, we urge HHS to require states' to use the information reported in plan provider directories to map provider locations and assess plans' compliance with geographic access standards.

Second, we recommend that HHS require states to monitor their contracted plans' compliance with the timely access standards set forth in our proposed § 438.68(b)(3), consistent with § 438.206(c)(1). Plans should be required to report regularly to the state

on the results of their own direct testing of their networks' compliance with timely access, including any corrective action the plan has taken to cure deficiencies uncovered in the direct testing. In addition, we urge the Secretary to develop, in consultation with states, providers, plans, consumer advocates, and other stakeholders, a standard methodology for plans to use in measuring compliance with timely access standards. California's Department of Managed Health Care, pursuant to a new statute, began this year requiring its licensed plans (including licensed Medicaid plans) to either survey their providers or audit their call records and encounter data.[52] We believe that HHS could work with states to adopt a similar approach that would collect timely access data from plans in a uniform way to facilitate states' oversight of plans compliance with timely access standards.

RECOMMENDATION: Amend § 438.207(b)(2) as follows:

(2) Maintains a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area. ***The MCO, PIHP, or PAHP shall demonstrate:***

(i) That its network meets the requirements of § 438.68 of this chapter, as documented by:

(A) A narrative description of its service area and the geographic area in which its enrollees (actual and/or projected) live and work and list all U.S. Postal ZIP Code numbers included in the service areas. To the extent possible, service areas should be delineated by political or natural boundaries.

(B) A map or maps upon which the information specified below is indicated by the specified system of symbols. The map(s) employed should be of convenient size and of the largest scale sufficient to include the applicant's entire service area and the surrounding area in which the actual or projected enrollees live or work. The use of good-quality city street maps or the street and highway maps available for various metropolitan areas, and regions of the State, such as are commonly available from automobile associations or retail service stations or from an internet or computer based program is preferred. The state shall ensure that the map or maps at a minimum show the following information:

(I) Such geographic detail, including highways and major streets, as is generally portrayed on the kinds of maps referred to above.

(II) The boundaries of MCO's, PIHP's, or PAHP's service area.

[52] CAL. STATE AUDITOR, *supra,* n. 51.

(III) The location of any contracting or plan-operated hospital and, if separate, each contracting or plan operated emergency health care facility. Hospitals are to be designated by an "H" and emergency care facilities by an "E."

(IV) The location of adult primary care providers, designated by a "P," and pediatric primary care providers, designated by "P-P." For convenience, the primary care providers within any single building or facility may be considered as being at one location within that area.

(V) The location of all other contracting or plan-operated health care providers including the following: Dental, designated by a "D." Pharmacy, designated by an "Rx." Laboratory, designated by an "L." Eye Care, designated by an "O." Adult Specialty care providers, designated by an "S." Women's Health Specialists, designated by a "W." Pediatric specialty care providers, designated by "S-P." Ancillary health care providers, designated by an "A." Providers of home and community-based long term services and supports, designated by "LTSS." Adult Behavioral Health, designated by "BH." Pediatric Behavioral Health, designated by "BH-P."

(C) Each MCO, PIHP, and PAHP shall attach an index to the map or maps described in subsection (B) which shows, for each symbol placed on the map for a hospital, and primary care provider, the following information:

(I) For each hospital, its total beds and the number of beds available to enrollees of the plan.

(II) For each symbol for primary care providers, the number of full-time equivalent adult and pediatric primary care providers represented by that symbol, and whether they are accepting new Medicaid patients.

(ii) That its network meets the timely access standards of § 438.206(c)(1)(i) of this subpart, as documented by:

(A) Annual reporting by the MCO, PIHP, or PAHP on its monitoring of its provider network as required by § 438.206(c)(1)(v) of this subpart to the state to ensure compliance with the standards set forth at § 438.206(c)(1)(i) of this subpart.

(I) MCOs, PIHPs, and PAHPs shall report annually to the state on compliance with the standards set forth at § 438.206(c)(1)(i) of this subpart in a manner specified by the Secretary. The reported information shall allow enrollees to compare the performance of plans and their

contracting providers in complying with the standards, as well as changes in the compliance of plans with these standards.
(II) The Secretary may develop standardized methodologies for reporting that shall be used by MCOs, PIHPs, and PAHPs to demonstrate compliance with this section and § 438.206(c)(1)(i) of this subpart. The methodologies shall be sufficient to determine compliance with the standards developed under this section and § 438.206(c)(1)(i) of this subpart for different networks of providers if an MCO, PIHP, or PAHP uses a different network for Medicaid managed care products than for other products. The Secretary shall consult with stakeholders in developing standardized methodologies under this paragraph.

d. § 438.207(c)(2)

We support HHS's addition of this provision, which will require states to review and certify contracted plans' networks for adequacy on an annual basis. This requirement should ensure that the networks of Medicaid plans are regularly and routinely reviewed for compliance, in addition to when they first begin serving the Medicaid market or experience other significant changes. Because provider relationships change frequently, and the needs of enrollees may also shift over time, such regular review is particularly warranted to ensure that networks remain adequate. This requirement also aligns with requirements for Marketplace plans, Medicare Advantage plans, and many state private market standards. We urge HHS to keep this important consumer protection in the final regulation.

e. § 438.207(d) – Certification of compliance

We appreciate that HHS has expanded this section to require not only that states certify compliance to HHS that their contracted plans' networks meet service availability requirements, but also that the states set forth an explanation and analysis to support the certification. We recommend that HHS clarify in this section that the certification extends not only to the availability of services requirements in § 438.206, but also to the network adequacy requirements of § 438.68. In addition, we urge HHS to specify in this section that the state post a copy of the certification report on its website and make paper copies available upon request. By making this report widely available to the public, HHS can facilitate greater oversight of Medicaid plans, and allow consumers and consumer advocates to evaluate the performance of their plan choices based on the information that is made available to the state.

RECOMMENDATION: Amend § 438.207(d) as follows:

> (d) State review and certification to CMS. After the State reviews the documentation submitted by the MCO, PIHP, or PAHP, the State must submit an assurance of compliance to CMS that the MCO, PIHP, or PAHP meets the State's requirements for availability of services, as set forth in § 438.206***, and network adequacy, as set forth in § 438.68***. The submission to CMS must include documentation of an analysis that supports the assurance of the adequacy of the network for each contracted MCO, PIHP or PAHP related to its provider network. ***The state shall post a copy of the certification report provided to CMS on its website and make the report available to the public in hard copy upon request.***

f. § 438.207(e) – Right to inspect documentation

We appreciate that HHS will continue to require states to provide the documentation underlying their certification of Medicaid plan networks to CMS upon request. We hope that CMS will more closely scrutinize this documentation to ensure that states are adequately monitoring their contracted plans, as recommended by the recent Office of Inspector General report.[53] Close scrutiny will also allow CMS to collect and share best practices in network adequacy and service availability monitoring among states. We suggest that HHS amend this section to explicitly require states to make the underlying documentation they collect in the monitoring process available to the public, in addition to CMS, upon request. We believe that by clearly specifying that this information is available to the public, HHS can facilitate greater public oversight of and input into state monitoring processes.

RECOMMENDATION: Amend § 438.207(e) as follows:

> (e) ~~CMS' r~~***R***ight to inspect documentation. The State must make available to CMS ***and the public***, upon request, all documentation collected by the State from the MCO, PIHP, or PAHP.

§ 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 who use LTSS. The additions to this section make significant strides toward ensuring that all Medicaid plan enrollees receive coordinated, appropriate care. We are, however, concerned that § 438.208(a)(2) would allow for overly broad exemptions from this section's requirements, thus diluting the effectiveness of this section. We request that HHS clarify and narrow this section so as to only allow exceptions in appropriate, limited circumstances.

[53] MURRIN, *supra* note 40 at 19-20.

a. §§ 438.208(b) – Care coordination

We particularly commend the changes that broaden the scope of § 438.208(b)(1) to extend Medicaid plans' responsibility for ensuring that enrollees have a regular source of care to recognize that a primary care provider may not be the most appropriate source for such care for certain populations. In addition, we strongly support continuing to ensure that Medicaid plans coordinate service between managed care and FFS, and among managed care plans, where applicable. Too often, where services are carved out from comprehensive managed care to FFS or another, specialty plan, enrollees' needs fall through the cracks, or they are pushed back and forth between potentially responsible entities. The language in proposed § 438.208(b)(2), (4) and (5) will continue to help to reduce these gaps and delays. We support HHS's suggestion in the preamble that, consistent with current industry practice, states require Medicaid plans to account for external community resources as they coordinate care. We request that HHS add specific language to § 438.208(b)(2) to this effect.

We also strongly support the addition of § 438.208(b)(3), which will explicitly require plans to make best efforts to perform an initial health assessment within 90 days of new enrollment. Initial health assessments are a key component to making Medicaid managed care successful, by ensuring that plans have the necessary information about new enrollees' health care needs in order to arrange for and coordinate their care. Too often, a person with chronic health care needs is newly enrolled into a plan and assigned to a primary care provider or care coordinator who is unfamiliar with his medical history. Unless that provider can quickly assess the enrollee's medical history and current needs, the provider will be ill-equipped to ensure that the enrollee is receiving appropriate care that is effective and not duplicative, and to initiate any necessary transition. The initial health assessment, together with the requirements of §§ 438.207(b)(4)-(5) should better ensure that plans quickly understand the health care needs of each new enrollee and arrange for that enrollee to receive appropriate services promptly. We strongly support a 90 day timeframe for these assessments, as 90 days strikes the right balance between providing flexibility for the plan and enrollee during the initial transition, but ensures that the enrollee's needs will be evaluated promptly. We suggest that HHS add specific language to § 438.207(b)(4) to specify that when an initial health assessment reveals that an enrollee is entitled to the transition of care protections set forth in § 438.62(b), the plan must initiate the transition of care procedures required by that section. To ensure coordination of all services, we also suggest language be added to §438.208(b)(4), similar to that in §441.720, that the results of the assessment and any service plan be coordinated with any other assessment and service plan required for Medicaid services.

We appreciate that HHS will continue to require plans to comply with existing rules governing privacy and confidentiality of personal health information. These protections are crucially important to ensuring that Medicaid managed care enrollees are able to access the services they need and cooperate with their plans' care coordination process. For many enrollees, knowing that their information will be kept strictly

confidential and will not be disseminated to an address or phone number where others may have access to their private health information is key to facilitating their participation in care coordination. Health information privacy also protects enrollees from potential discrimination or other harmful consequences. For example we are aware of several women whose parents or partners found out that they were using contraception when a care coordinator sent prescription information to their home addresses, causing embarrassment, family conflict, and in extreme cases, domestic violence. We recommend additional specific language to this section to ensure that plans and their care coordinators facilitate privacy protections that avoid these kinds of inadvertent disclosures.

RECOMMENDATION: Amend § 438.208(b)(6) as follows:

> § 438.208(b) *Care and coordination of services for all MCO, PIHP, and PAHP enrollees.* Each MCO, PIHP, and PAHP must implement procedures to deliver care to and coordinate services for all MCO, PIHP, and PAHP enrollees. These procedures must meet State requirements and must do the following:
> (1) Ensure that each enrollee has an ongoing source of care appropriate to his or her needs and a person or entity formally designated as primarily responsible for coordinating the services accessed by the enrollee.
> (2) Coordinate the services the MCO, PIHP, or PAHP furnishes to the enrollee:
> (i) Between settings of care including appropriate discharge planning for short term and long-term hospital and institutional stays;
> (ii) With the services the enrollee receives from any other MCO, PIHP, or PAHP; ~~and~~
> (iii) With the services the enrollee receives in FFS Medicaid***; and***
> ***(iv) With outside services and supports provided by organizations such as Protection and Advocacy organizations, legal services organizations, Aging and Disability Resources Centers, Centers for Independent Living, Area Agencies on Aging, United Way 311 lines, and local and state government resources***.
> (3) Provide that the MCO, PIHP or PAHP, within 90 days of the effective date of enrollment for all new enrollees, makes a best effort to conduct an initial assessment of each enrollee's needs, including subsequent attempts if the initial attempt to contact the enrollee is unsuccessful.
> (4) Coordinate with the State or other MCOs, PIHPs, and PAHP serving the enrollee the results of any identification and assessment of that enrollee's needs to prevent duplication of those activities***, and, consistent with § 438.62(b) of this chapter, initiate the plan's transition of care policy***.
> (5) Ensure that each provider furnishing services to enrollees maintains and shares, as appropriate, an enrollee health record in accordance with professional standards.
> (6) Ensure that in the process of coordinating care, each enrollee's privacy is protected in accordance with the privacy requirements in 45 CFR parts 160 and

164 subparts A and E, to the extent that they are applicable. ***In addition, the MCO, PIHP or PAHP shall:***

(i) Ensure that enrollees may receive health care service plan communications containing medical information at a specific mail or email address or specific telephone number, as designated by the enrollee.

(ii) Inform enrollees of their right to designate the location where plan communications containing medical information will be communicated pursuant to paragraph (i).

b. Additional Services for Enrollees who need LTSS or have special health care needs

We appreciate the recognition that individuals who need, not just those who receive, LTSS and those who have special health care needs generally have more care coordination needs and protections. We especially support the reference to the person-centered-planning requirements in § 441.301(c)(1) and (2). We generally support the provision regarding assessments, but are concerned that there is no protection against conflicts of interest in the assessment process. The assessment will help form any treatment plan and if the process is not free from influence from utilization review or other financial influences that could discourage service utilization, the process would not accurately reflect the individual's needs. Managed care enrollees complain that assessments and care coordination are often used as tools to cut or limit services. Assessment are also commonly used as a tool for budgeting and managed care plans have used them inappropriately to limit services in solely to save money. plans. Therefore, we recommend changes to further protect against conflicts of interest and better ensure that assessment processes accurately reflect the person's needs.

RECOMMENDATION: Amend § 438.208(c)(2) as follows:

(2) *Assessment.* Each MCO, PIHP, and PAHP must implement mechanisms to comprehensively assess each Medicaid enrollee identified by the State (through the mechanism specified in paragraph (c)(1) of this section) and identified to the MCO, PIHP, and PAHP by the State as needing LTSS or having special health care needs to identify any ongoing special conditions of the enrollee that require a course of treatment or regular care monitoring. The assessment mechanisms must ***be free from conflicts of interest related to service utilization and*** use appropriate health care professions or individual meeting LTSS service coordination requirements

§ 438.210 - Coverage and authorization of services

We commend HHS for making several key updates to this section to ensure that Medicaid managed care plans use appropriate criteria when determining whether to provide services to particular enrollees and in what amount, duration, and scope.

a. § 438.210(a)(1)-(3) – Amount, duration, and scope

We appreciate that in the first three paragraphs of § 438.210(a), HHS will continue to explicitly require states to identify the amount, duration and scope of coverage in their contracts with plans. We also applaud HHS for explicitly requiring states' contracts with plans to ensure that contracted plans cover services in an amount, duration, and scope that is no less than that provided to FFS Medicaid beneficiaries. This provision will go a long way toward ensuring that Medicaid managed care enrollees do not receive a lesser scope of services than their FFS counterparts, and will also ensure greater consistency among plans in a state.

b. § 438.210(a)(4)

We appreciate that HHS has placed the requirements for plans' limitations on services in a separate paragraph. Given the importance of such limitations on enrollee's appropriate access to care, we believe that separating them is warranted to ensure that they are not lost in a larger section. We agree that plans may limit services according to the state's medical necessity definition. We also agree that some additional limits may be imposed by plans for the purposes of utilization control. We are concerned, however, that this section gives plans far too much leeway to develop utilization review criteria. While we appreciate that, as HHS sets forth in the preamble, plans have discretion to set utilization control measures, we do not believe that this discretion is unbounded, but that rather that it must be founded in a clinical standard of care. We suggest clarifying the language in this section and adding significant detail to ensure that utilization controls do not arbitrarily or inappropriately limit access to care.

We appreciate that HHS links utilization control methods to the amount, duration and scope guidelines described earlier. We are concerned, however, that these guidelines are too broad to provide adequate guidance to plans in developing their utilization review criteria. We suggest that HHS adopt language in this section, adapted from California's Knox-Keene Act, to ensure that any utilization control methods and criteria are based on the clinical standard of care, are regularly reviewed and updated, and are available both to the public and to providers and enrollees. See Cal. Health & Safety Code § 1363.5(b).

In addition, we suggest adding three provisions to address frequent problems in Medicaid managed care. First, we suggest specifying that plans may not use utilization control criteria that require an enrollee to show improvement to continue receiving services; particularly in the area of LTSS, many services are necessary to help enrollees retain and maintain their current level of functioning and avoid regression. For example, it makes no sense to allow Medicaid managed care enrollees with Crohn's disease to receive treatment for the acute stages of the disease, but not cover maintenance treatment once the enrollee has gone into remission. Refusing coverage for maintenance purposes would have the perverse effect of requiring enrollees to

regress back into an acute stage of the disease before they could access treatment. Such policy is inconsistent with public health goals and the amount, duration and scope requirements of the Medicaid Act. Rather plans must treat conditions when they are acute and also maintain the health and well-being of those with chronic conditions over the long term. HHS should clarify that maintenance services must absolutely be provided by Medicaid plans.

Second, we suggest adding language that requires plans to place a priority on safe and effective treatments, and delivering care in a manner that is least intrusive and least restrictive, consistent with the level of care that is clinically appropriate for enrollees. Too often, enrollees are required to undergo a more-invasive and less effective treatment for their illness or condition simply because it is cheaper. For example, enrollees with hepatitis C are often required to undergo the pre-2014 typical treatment with a combination of interferon and ribavirin, which requires multiple injections each week and frequently causes significant side-effects, even though new treatments are available that do not require any injections and have almost no side-effects. The new treatments also have an over 90% cure rate for hepatitis C over 12 weeks compared to a 50% cure rate for the older treatment combinations, which require a minimum of 24 weeks of treatment. Plans must cover the new treatments, even though they may cost more than the older regimens. We urge HHS to work with states to stop plans from using utilization criteria that prioritize cost over effectiveness and overall value of treatment.

Third, we recommend adding language that requires plans to consider individual factors, including tolerance for side effects, differences in treatment types, and the patient's ability to adhere to the recommended treatment regimen. Our suggested language is adapted language from the recent ACA FAQs put forth by HHS in conjunction with other federal departments.[54] While the language in that section of the FAQ related to appropriate considerations in authorizing contraception, they are equally relevant to other services and treatments. HHS should clarify that these factors are to be considered in the utilization review process.

We greatly appreciate that HHS has, for the first time, added specific language to this section aimed at ensuring that plans guarantee freedom of choice for family planning services. The Medicaid Act is clear that family planning services must be "furnished (directly or under arrangements with others) to individuals of child-bearing age (including minors who can be considered to be sexually active) who are eligible under the State plan and who desire such services and supplies." 42 U.S.C. § 1396d(a)(4)(C). Elsewhere, HHS has interpreted this provision to require that states ensure that Medicaid beneficiaries are "free from coercion or mental pressure and free to choose

[54] DEPTS. OF LABOR, HEALTH & HUMAN SERVS., AND THE TREASURY, FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION (PART XXVI) 4 (2015), *available at* http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf.

the method of family planning to be used." 42 C.F.R. § 441.20. Taken together, these provisions clearly require all family planning services to be available to Medicaid managed care enrollees without prior authorization. Quality family planning requires that enrollees must be able to select the contraceptive method that works best for them. Only when an individual can make that decision freely will they use the method consistently and effectively. When individuals use a contraceptive method consistently, unintended pregnancies are significantly reduced.[55] We disagree with HHS's statement in the preamble that states and plans have the "ability to apply medical necessity criteria for an individual's request for family planning services but provides that utilization controls that would interfere with an enrollee's freedom to choose the method of family planning would not be permitted." 80 F.R. 31138. Given the individualized nature of these services, enrollees must be absolutely free to choose the methods of family planning that will work best for them, without any restriction. The distinction that HHS attempts to draw in the preamble between medical necessity criteria and utilization controls is unworkable—by definition, family planning services are medically necessary for enrollees of child-bearing age who desire them. HHS should not allow plans to impose any form of prior authorization or medical management requirements on family planning services beyond a cursory assessment to confirm that the enrollee is of child-bearing age and desires family planning services.

Too often, Medicaid managed care enrollees are not afforded free choice. Rather, many enrollees are restricted, for example, to one type of hormonal birth control pill without prior authorization, even though the FDA has approved dozens of hormonal pills containing different levels and combinations of hormones that work in different ways, and have different side-effects. The most common type of birth control bill, a monophasic estrogen-progesterone combination bill, may not be the preferred choice for a woman who would like to reduce her periods, who is breast-feeding, or who has previously experienced side effects on that pill. She should not have to go through utilization review before obtaining a different birth control pill that is a better fit for her needs. Further, some states and plans have interpreted the freedom of choice provisions narrowly, and have only made actual contraception available without prior authorization, for example, but not the provider visits needed to insert an IUD or fit a diaphragm or follow-up after a vasectomy. We suggest that HHS revise the language in this section to make very clear to states and plans that Medicaid managed care plans must cover all family planning services without prior authorization.

RECOMMENDATION: Amend § 438.210(a)(4)(ii)(A) & (C) as follows:

(a)(4). . .

[55] CENTERS FOR DISEASE CONTROL AND PREVENTION, HHS OFFICE OF POPULATION AFFAIRS, PROVIDING QUALITY FAMILY PLANNING SERVICES: RECOMMENDATIONS OF CDC AND THE U.S. OFFICE OF POPULATION AFFAIRS, 64 Morbidity and Mortality Weekly Report 1 (April 25, 2014), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6304a1.htm?s_cid=rr6304a1_w.

(A) The services furnished can reasonably achieve their purpose, as required in paragraph (a)(3)(i) of this section~~;~~***, such that the criteria or guidelines used by the MCO, PIHP, or PAHP, or any entities with which it contracts for services that include utilization review or utilization management functions, to determine whether to authorize, modify, or deny health care services shall:***

(I) Be developed with involvement from actively practicing health care providers;

(II) Be consistent with sound clinical principles and processes, generally based on large quantities of evidence from empirical studies (i.e., evidence based), but where such evidence is lacking due to the condition or unique nature of a patient's needs or illness, the standards should be based on a clinician's experience in practice, and must accommodate treatments which maximize, maintain, or reduce the degeneration of functional status;

(III) Emphasize that care must be delivered in the safest and least intrusive manner and least restrictive setting, and as necessary to facilitate living in the community;

(IV) Include considerations such as severity of side effects, differences in permanence and reversibility of treatments, and ability to adhere to the appropriate use of the item or service, as determined by the attending provider;

(V) Be evaluated, and updated if necessary, at least annually;

(VI) If used as the basis of a decision to modify, delay, or deny services in a specified case under review, be disclosed to the provider and the enrollee in that specified case;

(VII) Be available to the public upon request. A MCO, PIHP or PAHP shall only be required to disclose the criteria or guidelines for the specific procedures or conditions requested; and

(VIII) Ensure the disclosure required by paragraph (VI) of subdivision (a)(4)(ii) is accompanied by the following notice: "The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual need."

. . .

(C) Family planning services***—including all FDA-approved contraceptive drugs and devices, voluntary sterilization procedures, patient education and counseling on contraception, and follow-up services related to the drugs, devices, products, and procedures covered under this subdivision, including, but not limited to, management of side effects, counseling for continued adherence, and device insertion and removal—***are provided ~~in a manner that protects and enables the enrollee's freedom to choose the method of family planning to be used~~ ***without prior authorization, restriction or delay*** consistent with § 441.20.

c. § 438.210(a)(5) – Medical necessity definition

We commend HHS for expanding this section to give more guidance to states and plans in defining medical necessity. We strongly support HHS's decision to include—for the first time—an explicit provision that requires plans to comply with the EPSDT requirements of the Medicaid Act. 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 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. For example, we recently worked with a state that provided DME that was medically necessary inside the home, or outside the home for community access in its FFS program. Its contracted plans, however, were only providing DME that could be used inside the home. To avoid this kind of legal violation, we suggest that HHS add specific language to this section to clarify that 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.

Again, we very much appreciate the specific language HHS added to this section to account for EPSDT. We suggest that HHS remove the word "chronic" from this section, as it is inconsistent with the EPSDT statute, which requires states to correct or ameliorate all conditions, not only chronic ones. *See* 42 U.S.A. § 1396d(r)(5).

We particularly appreciate that HHS has included specific language that will require plans to address the ADA's integration mandate in their provision of LTSS in § 438.210(a)(5)(iii)(D). We are concerned that the language in this section is too broad, however. We recommend amending the language in this paragraph to make it consistent with the language in the recently released Medicaid HCBS regulations at § 441.301(c)(4)(i). This language draws upon long-standing ADA and Rehabilitation Act regulations that require state programs to maximize community integration. *See* 28 CFR §§ 41.51(d) &35.130(d).

RECOMMENDATION: Amend § 438.210(a)(5) as follows:

> (5) 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*** cover***ed in the contract***~~ing services~~ that address:. . .
> (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~~.

d. § 438.210(b) – Authorization of services

We commend HHS for significantly expanding this section to account for the needs of enrollees using LTSS and behavioral health. We commend HHS for specifically requiring plans to authorize LTSS based on an enrollee's current needs assessment and consistent with the person-centered service plan. Too often, plans ignore enrollees' needs assessments and service plans and deny LTSS at every opportunity—forcing enrollees to appeal denials of their LTSS every time the services are up for reauthorization, even when their condition has not changed since the last approval. We appreciate that the language in this section will make clearer that such denials are not allowed in Medicaid managed care, and we suggest a few clarifications to make this intent even more clear. We also suggest that HHS broaden the language in § 438.210(b)(2)(iii) to clarify that other treatments for chronic conditions should take into consideration the enrollee's needs assessment and treatment plan, and that plans may not arbitrarily reduce or deny services for chronic conditions absent a change in condition, similar to the requirements for LTSS. Finally, we suggest language on authorization that we feel is critical if the authorization and appeal procedures are to work in tandem in the best interests of beneficiaries.

We further recommend that HHS add language to this section to clarify that Medicaid plans must disseminate their written procedures for service authorization to the state and to their providers, and that plans must make these procedures available to the public upon request. We have provided suggested edits to this section based on California's Knox-Keene Act. *See* Cal. Health & Safety Code § 1363.5(a). We also suggest that HHS affirm in this section that plans may not use prior authorization for family planning services, as described in greater detail above (see § 438.210(a)(4)).

In addition, we recommend that the timing of reauthorization requests and approvals be set so that, if the health plan terminates or reduces the service or course of treatment, the enrollee and provider will receive notice of the termination or reduction in a timely manner that will enable continuation of services pending appeal. Our suggestions for amending this subsection should be read in tandem with our suggestions for amending § 438 420, Continuation of benefits while the MCO, PIHP, or PAHP appeal and the State fair hearing are pending.

Finally, we suggest that HHS add language to this section to set forth a plan's responsibilities regarding non-emergency transportation services. A "medical necessity" standard is not the right fit for non-emergency transportation, but too often, plans require a showing of medical necessity before transportation can be authorized. As long as the underlying service or appointment is medically necessary and an enrollee does not have appropriate transportation to access that medically necessary care, transportation should be authorized. We recommend that HHS make these requirements explicit in the regulation.

RECOMMENDATION: Amend § 438.210(b) as follows:

(b) *Authorization of services.* For the processing of requests for initial and continuing authorizations of services, each contract must require—

(1) That the MCO, PIHP, or PAHP and its subcontractors have in place, and follow, written policies and procedures. ***The MCO, PIHP, or PAHP shall disclose to the state and to network providers the process the plan, its contracting provider groups, or any entity with which the plan contracts for services that include utilization review or utilization management functions, uses to authorize, modify, or deny health care services under the benefits provided by the plan, including LTSS. The MCO, PIHP, or PAHP shall also disclose those processes to the public upon request.***

(2) That the MCO, PIHP, or PAHP—

(i) Have in effect mechanisms to ensure consistent application of review criteria for authorization decisions.

(ii) Consult with the requesting provider for medical services when appropriate.

(iii) Authorize LTSS ***and other services for chronic conditions*** based on an enrollee's current needs assessment and consistent with the person-centered service plan ***and not arbitrarily reduce, modify, or deny previously authorized services when the enrollee's needs have not changed***.

(iv) Ensure that initial and reauthorizations of services clearly inform the enrollee and provider of the period of authorization, including the date on which the period of authorization ends and the deadline for requesting reauthorization of services such that services will continue without interruption;

(iv) Shall not require prior authorization for family planning services and supplies consistent with paragraph (a)(4)(ii)(C) of this section.

(v) Shall provide non-emergency transportation services whenever an enrollee needs transportation to receive covered, medically necessary services.

(3) Reauthorization requests. All requests for reauthorization or continuation of a service must be submitted by the prescribing providers at least 10 calendar days prior to the end of the current authorization period for services to continue without interruption pending the decision on reauthorization.

(i) If the prescribing provider submits the request at least 10 calendar days prior to the end of the current authorization period and the request is approved, there must be no break in service and the service must be authorized beginning on the first day after the end of the authorization period.

(ii) If the request is submitted at least 10 calendar days prior to the end of the current authorization period but the MCO, PIHP, or PAHP does not make a decision approving reauthorization prior to the end of the current authorization period, then the service authorization must continue without interruption until 10 days after a notice of change in services is sent by the MCO, PIHP, or PAHP.

(iii) If the prescribing provider submitted the request at least 10 calendar days prior to the end of the current authorization period and requested services are terminated or authorized in an amount, duration, or scope less than that requested

(a) the effective date of the change in services shall be no sooner than 10 days after the date the notice is mailed;

(b) the enrollee will be provided notice of the adverse coverage determination as provided under 42 C.F.R.§ 438.408; and

(c) the MCO, PIHP, or PAHP must ensure the continuation of benefits as required under 42 C.F.R. § 438.420.

OPTION A:

(iv) For LTSS and other services for chronic conditions, if the request for reauthorization is not submitted at least 10 calendar days prior to the end of the current authorization period, the plan shall, 10 calendar days prior to the end of the current authorization period, send written notice to the enrollee stating that the authorization period will be extended for 10 calendar days after the end of the current authorization period, and that services will terminate if no reauthorization request is received by the last day of said extension period. The notice shall specify the address and fax number to submit a reauthorization request.

OPTION B:

(iv) ***For LTSS and other services for chronic conditions, when an enrollee has been prescribed a covered service that is subject to prior authorization and that is:***

(A) for a chronic condition;

(B) is prescribed on an ongoing basis or with no specific ending date; or

(C) can cause serious harm to the enrollee if interrupted, the MCO, PIHP or PAHP must provide notice to the enrollee before the expiration of prior authorization for the service. The notice must be provided no more than 40 days, or less than 30 days, prior to the expiration of prior authorization for the service. In the event that the period of authorization is less than 30 days, the notice shall be issued upon authorization.

(v) The notice must:

(A) identify the service,

(B) list the contact information for the provider who previously prescribed it,

(C) inform the enrollee when authorization is ending, and

(D) explain that the service must be prescribed again by an authorized provider at least 10 days prior to expiration in order to prevent possible disruption.

(~~3~~4) That any decision to deny, **terminate or reduce** a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested, be made by a health care professional who has appropriate expertise in addressing the enrollee's medical, behavioral health, or long-term services and supports needs.

e. § 438.210(c) – Notice

We appreciate that HHS has kept the general structure of this subdivision. The protections set forth are crucially important to enrollees in understanding why a service request was denied, and how enrollees and providers can contest those denials. We also appreciate that HHS has amended this section to make clear that notice must be provided in writing to both the enrollee and the provider.

a. § 438.210(d) – Timeframe for decisions

We also commend HHS for changing the time period for expedited review of adverse benefits determinations from 3 days to 72 hours. As HHS notes in the preamble, using a 72 hour standard is consistent with the timeframes in other coverage programs. It will also avoid potential undue delays over weekends or holiday periods.

§ 438.214 - Provider selection.

a. Uniform credentialing and recredentialing policies

We strongly support the addition to subsection (b)(1) that provides more specificity about what the credentialing and recredentialing policies must address. We agree with the inclusion of acute, primary, behavioral, substance use disorder, and LTSS providers. We believe this list must also include reproductive health providers because such policies would help identify women's health care providers who refuse to provide certain services for religious reasons. For example, a plan's network may include several OB/GYNs but if they all work within religiously affiliated hospitals, critical covered services will not be available. Information acquired during the credentialing process could help ensure that the managed care entity has full knowledge of the provider network's actual provision of services (as opposed only to types of providers) and can therefore address any gaps in services where necessary and refer women to alternate providers if services have been refused.

RECOMMENDATION: Amend § 438.214(b)(1) as follows:

(1) Each State must establish a uniform credentialing and recredentialing policy that addresses acute, primary, behavioral, substance use disorders, ***women's health care services,*** and LTSS providers, as appropriate, and require each MCO, PIHP and PAHP to follow those policies.

b. Nondiscrimination

Subsection (c) provides that managed care entities may not discriminate against providers that serve high-risk populations or specialize in conditions that require costly treatment. This nondiscrimination provision subsection is incomplete and should include a more general nondiscrimination provision to protect providers from other forms of

discrimination. Providers should be fully protected against discrimination by managed care entities and not have this section be fully inclusive of such protections makes it incomplete. An array of providers is important and nondiscrimination is key to providing such an array to meet the needs of enrollees. Given that § 1557 of the ACA applies to all plans, we also believe that including reference to the protected classes of individuals pursuant to § 1557 is important to note that the nondiscrimination protections apply not only to enrollees but also network providers. We therefore suggest that subsection (c) be divided into two subsections to include this general nondiscrimination provision.

RECOMMENDATION: Amend § 438.214(c) as follows:

(c) *Nondiscrimination.* MCO, PIHP, and PAHP provider selection policies and procedures, consistent with §438.12, must not:

(1) discriminate against particular providers that serve high-risk populations or specialize in conditions that require costly treatment.

(2) discriminate against particular providers on the basis of the provider's (or provider's staff's) race, color, ~~or~~ national origin, language, disability, age, sex, gender identity, or sexual orientation.

§ 438.230 - Subcontractual relationships and delegation

Private contracting does not relieve states of their responsibility to ensure compliance with federal legal requirements such as due process and nondiscrimination protections. The state Medicaid agency remains the "single state agency" responsible for assuring the proper implementation of the Medicaid law, regulations, and guidelines and that authority cannot be delegated or impaired.[56]
Therefore, we recommend that HHS expressly require subcontracts and delegations to specify that the subcontracting entity or individual will comply with federal law.

RECOMMENDATION: Add new subsections (d and e) as follows:

(d) In entering into subcontracts, MCOs, PIHPs, PAHPs, PCCMs and PCCM entities must not:

(1) Discriminate against particular providers that serve high-risk populations or specialize in conditions that require costly treatment.

(2) Discriminate against particular providers on the basis of the provider's (or provider's staff's) race, color, national origin, nor use any policy or practice that has the effect of discriminating on the

[56] *See* 42 U.S.C. § 1396a(a)(5); 42 C.F.R. § 431.10(e). See also, e.g., *Hillburn v. Maher*, 795 F.2d 252 (2d Cir. 1986) (noting that the single state agency requirement derives from the desire to focus accountability for program operation).

basis of race, color, or national origin, language, disability, age, sex, sexual orientation, or gender identity.

language, disability, age, sex, gender identity, or sexual orientation.

(e) Compliance with applicable laws. Subcontracts and delegations with MCOs, PIHPs, PAHPs, PCCMs and PCCM entities must specify that the individual or subcontracting entity:

(1) Will not discriminate against individuals or entities on the basis of race, color, or national origin, language, disability, age, sex, sexual orientation, or gender identity, and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin, language, disability, age, sex, sexual orientation, or gender identity.

(2) Comply with all applicable Federal and State laws and regulations including Title VI of the Civil Rights Act of 1964; Title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990 as amended; section 1557 of the Patient Protection and Affordable Care Act, and the United States Constitution.

§ 438.242 - Health information systems

We appreciate HHS' recognition of the importance of transparency in stakeholder engagement and oversight of Medicaid managed care programs. In keeping with new public posting requirements (e.g., §§ 438.10(c), 438.66, 438.68(e), 438.364(b)(2), and 438.602(g)) we recommend HHS expressly make health information systems data available to community stakeholders. For example, data collected on utilization, claims, grievances and appeals, and disenrollment for reasons other than a loss of Medicaid eligibility can be vital for oversight and quality improvement efforts. Therefore, we recommend HHS expressly make health systems data more easily available.

RECOMMENDATION: Amend § 438.242(b)(4) as follows:

(4) Make all collected data available to the State, ***the Medical Care Advisory Committee established under §431.12 of this chapter or an advisory committee with similar membership, the stakeholder consultation group specified in § 438.70, as provided under § 438.602(g); through the state Web site established pursuant to § 438.10(c)(3)*** and upon request to CMS, as required in this part.

SUBPART E - Quality

§ 438.310 - Basis, scope and applicability

NHeLP generally supports HHS's 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 cross-reference to § 438.208, because adequate care coordination and continuity protections when 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 plan 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.

The proposed definition of "quality" appears clinically focused and makes no clear reference to covered long-term services and supports, which should also be included. For example, the "quality" definition refers only to "health" outcomes and "clinically significant results." CMS alluded to this problem in 2012 guidance on applying EQR protocols to LTSS, identifying terms that "may be narrowly construed to reflect medical services" and providing a set of expanded definitions that better incorporate the concepts critical to LTSS.[57] We suggest that HHS draw from this guidance to review the definitions in this section and revise them to reflect what quality means with respect to LTSS. The definitions should reflect a broad understanding of health and well-being, including both "quality of life" and the "ability to independently live and engage in community life." We recommend that HHS include a broad definition of the term "outcome" that recognizes the factors important to LTSS.

Similarly, the definition of "external quality review" refers to "health care services." We suggest either defining the term "health care services" to include all Medicaid services covered under the contract, including LTSS, or by deleting "health care" and adding language to clarify that EQR refers to *all* services covered under the managed care contract, including LTSS if covered.

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 includes the types of direct testing described in § 438.358(b)(4) (network adequacy

[57] CMS, *Application of Existing External Quality Review Protocols to Managed Long Term Services and Supports*, 2-3 (2013), http://medicaid.gov/medicaid-chip-program-information/by-topics/delivery-systems/downloads/cmcs-eqr-protocols.pdf.

validation). We also suggest that HHS define the term "direct testing" in the regulations for better clarity.

RECOMMENDATIONS: 1. Amend the definitions 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)***.

2. Amend the definition of "quality" in § 438.320 by striking the term "health" prior to the word "outcomes," and add a definition for "outcomes":

> 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…
>
> ***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.***

3. Add a definition of "direct testing" 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.***

4. Amend the definition of "validation" 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.

§ 438.330 - Quality assessment and performance improvement program

Generally, we support application of these requirements to PAHPs and establishment of a process to select federally required core measures and 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 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 recommend that HHS provide additional requirements to flesh out the stakeholder engagement and public comment process for selecting core national measures and PIP topics. We suggest that HHS, at the very least, prescribe 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 measures. 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 why a state may obtain an exception and setting time limits on how long exemptions could last without review and extension. We agree with HHS that legitimate exceptions could include not collecting a measure that is irrelevant to the managed care covered population in a state or that measures the quality of a service not covered by or relevant to the managed care contract.[58]

We strongly disagree with the preamble suggestion that a state might qualify for an exemption if it surpasses a defined threshold for multiple years.[59] For many measures, such as certain vaccinations or the frequency of “never events,” a threshold of 90% would not be considered successful. Even if HHS set appropriate thresholds for each national measure, the exemption process leaves no mechanism to prevent against a 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 exempt its managed care entities from reporting that metric could undermine HHS’s broader efforts to identify and reduce health disparities across key demographic groups. If HHS were to go forward and allow this type of exemption, it should require states that meet the percentage to also demonstrate that no significant disparities exist and it should limit the exception to no more than two years.

[58] 80 Fed. Reg. 31150.
[59] *Id.*

We encourage CMS 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 commend HHS for requiring PCCM entities to establish and maintain mechanisms to detect over- and under-utilization 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 care. While we recognize that LTSS performance measurement 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. In the preamble, HHS also acknowledges the importance of self-direction, encouraging states whose MLTSS programs include a self-directed option to include measures specific to self-direction. We urge HHS to strengthen the regulation to require such measures, if applicable. As HHS alluded to in its 2013 MLTSS guidance to states, there are potential concerns and opportunities related to self-direction as states expand Medicaid managed care. We believe it is essential to have quality measures to assess opportunities, supports, and outcomes related to self-direction.

RECOMMENDATIONS: 1. Amend § 438.330(a)(2)(ii) to narrow the state exemption process by establishing a 2-year time limit for exemptions, provide states with limited pathways to receive exemptions based only on (1) if the measure is not applicable to the covered population; or (2) if the measure is only relevant to a service or services not covered in the MCO contract. If HHS 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.

2. Amend paragraph (c)(4) as follows:

> (4) *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 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 Medicaid 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 latter approach.

First, the process of setting standards for a public program like Medicaid 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.

Second, 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."[60] To the extent they are available for purchase, they may be quite expensive. If being used in Medicaid programs, private entities' standards and measures must be readily and publicly available at no or nominal cost, or separate standards should be determined by the state after a robust stakeholder engagement process. Similarly, if the state accepts deeming by private entities, 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.

Third, HHS has included no indication that this accreditation process is specific to the Medicaid business line of a participating MCO, PIHP or PAHP as opposed to other private business lines. Medicaid populations are different from commercial groups and have unique needs. If states are allowed to use an industry-wide accreditation standard, it may not be a reliable predictor of how well that plan will be prepared to manage care for Medicaid populations, especially with regards to 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.

Fourth, HHS must not allow the accreditation requirement to undermine other quality assurance efforts. This expansion of required accreditation, which is written to strongly encourage states to make use of private accrediting agencies, could easily end up

[60] E-mail from Judy Wackenhut, Dir. Sales & Business Dev., URAC, to David Machledt, Policy Analyst, Nat'l Health Law Program (July 8, 2015, 11:45AM EST) (on file with NHeLP).

replacing most of the key elements of EQR, and perhaps in a less timely, less accountable and less effective manner. We 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.*

Finally, we support the provision clarifying that the State has responsibility for final approval on accreditation, consistent with the requirements of the Single State Agency.

RECOMMENDATION: 1. To the extent that HHS permits states to deem compliance based on private accreditation by an authorized entity, the regulations must ensure that those private entities' standards and measures for Medicaid plans are readily and publicly available at no or nominal cost. Alternatively, the evaluation standards should be determined by the state after a robust stakeholder engagement process. If the state accepts deeming by private entities, 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.

2. HHS should only permit accreditation from a private entity if that accreditation process is specific to the Medicaid business line of that MCO, PIHP or PAHP.

§ 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 star rating system can also encourage transparency and even strengthen the oversight process. However, a poorly designed or executed star rating system can do quite the opposite by potentially giving plans an undeserved imprimatur of excellence.

Any effective star 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, a clear and transparent process for addressing risk adjustment is an essential part of 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 fee-for-service populations.

Second, neither of the quality ratings systems that HHS proposes include extensive coverage of LTSS. The preamble section discussing the quality rating system does not mention LTSS at all, despite the fact that nothing in the regulation indicates that managed LTSS programs would be exempt or carved out from the rating system. We are not advocating that LTSS be carved out, but rather that HHS require consideration of the role of LTSS in the design of a Medicaid quality rating system.

Third, HHS should clarify what the term "affordability" means. Because out-of-pocket expenses for Medicaid beneficiaries should not vary by health plan, 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 has a lower capitated rate 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 star rating system might not reflect that fact. We believe the term "efficiency" better captures the triple aim of better care experience, better health outcomes, and affordability. We recommend that CMS delete "affordability" as a component of the star rating system or, in the alternative, clarify that affordability specifically refers to an individual's ability to meet 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.[61] 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.[62] 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 CMS approval.

RECOMMENDATIONS: **1**. Amend paragraph (a)(2)(iii) to delete "affordability" as a component of a quality rating system as follows:

> (a)(2) The quality rating system must be based on the following three components:
> (i) Clinical quality management ***and, if applicable, management of LTSS*****.**

[61] *See above,* § 438.330(a)(2).
[62] 42 C.F.R. §§ 431.408 - 416.

(ii) Member experience.
(iii) Plan efficiency~~, affordability,~~ and management.

2. Add paragraph (a)(4) to ensure consumers will understand how to use the tool:

(a)(4) 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.

3. 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:

(c) *Alternative quality rating system*. Upon CMS 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. ***CMS 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.***

§ 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 comprehensive quality strategy. We ask HHS to clarify the relationship between the state-chosen quality metrics described in § 431.502(b)(2) and the state-selected metrics described in § 438.330(a)(2). For example, it is not clear whether or how metrics selected in the CMS public comment process described in § 438.330(a)(2) would apply to a state's Medicaid FFS system.

§ 438.350 - External Quality Review

HHS has proposed several 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 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 elaborate on these concerns below.

We support the proposed provision extending EQR to cover PAHPs and recognizing that 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 oversight method. 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.

RECOMMENDATIONS: 1. Add the following language to paragraph (a)(2):

> (2) 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.

2. Add the following language to paragraph (b):

> (b) ***Consistent with the requirements of § 438.3(r), a*** 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.*** . ~~If an EQR is performed,~~ ***For EQR of such entities***, 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.

Because EQR may be required of certain PCCM entities, we suggest that 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's proposed changes. Similar additions may also be appropriate for other sections throughout the EQR regulation.

We support the provision that prohibits entities that conduct accreditation reviews on contracting MCOs, PIHPs, PAHPs, or PCCM entities from acting as EQROs.

RECOMMENDATIONS: **1**. Throughout paragraph (c) add "PCCM entity" to the list of managed care organizations, such that "MCO, PIHP, or PAHP" becomes "MCO, PIHP, ~~or~~ PAHP***, or PCCM entity***."

2. Add the following language to paragraph (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—

3. Add the phrase "or expected" to paragraph (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, including the requirement that states follow an open, competitive procurement process. The regulations at 45 C.F.R. part 75 require that requests 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: **A**dd the following sentence to paragraph (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 the State Web Site provide a reasonable public comment period of at least 30 days prior to beginning the bidding process.***

§ 438.358 - Activities related to external quality review

As Medicaid increasingly employs capitation and accountable care as a 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 that EQR 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. Two HHS Office of the Inspector General (OIG) reports cited in the preamble demonstrate the efficacy and importance of directly testing provider networks for compliance, access and availability.[63] 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' requirement that state's use EQR to validate network adequacy, but do not believe it goes far enough. As the OIG reports revealed, an absence of violations can indicate a weak and passive review process rather than exceptional plan performance. We believe it unlikely that managed care compliance reviews 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, provision of language services and accommodations for individuals with disabilities, and service authorization. Under our recommendation, a state would have to conduct annual direct testing of at least a subset of managed care standards set forth in Part D and § 438.330. This requirement would stand apart from the existing requirement to require comprehensive compliance review at least every three years. Directions as to how states or HHS might 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 protocol, this oversight mechanism is important enough that it should be included 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

[63] HHS OIG, *State Standards for Access to Care in Medicaid Managed Care* (Sept. 2014); HHS OIG, *Access to Care: Provider Availability in Medicaid Managed Care* (Dec. 2014).

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 does not clearly encompass the other two fundamental components. HHS's 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)."[64] That review occurs only once in three years, not annually. Provider accessibility and timely availability should be measured by an external reviewer *at least* annually, and 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 three 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, a review of disenrollments (both member and plan-initiated) as well as denials of health services (including partial denials−where fewer services were provided than what the provider requested) should be incorporated into the EQR on a mandatory basis. Finally, 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 experience surveys and focus groups are currently optional EQR related activities.

RECOMMENDATIONS: 1. Amend § 438.358(b)(3) as follows:

> (b)…(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, PAHP***, and PCCM entity*** network adequacy during

[64] 80 Fed. Reg. 31156.

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.

(8) A review and analysis of disenrollments, denials (including partial denials) of services in the preceding 12 months with each MCO or PHP, to identify systemic problems and recommend potential remedies.

2. Amend paragraph (c) to conform with the above 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 intended to strengthen the EQR process. The only example described in the preamble explaining how this new process would work frankly raises more questions than it answers.[65] We strongly oppose the proposed changes to the non-duplication provision, and recommend that HHS abandon its proposed expansion of this 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

[65] *See* 80 Fed. Reg. 31156-7.

nonduplication provision because the private accreditation review often encompasses an MCO or PIHP's commercial lines of business.[66] 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.[67] 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. First, the preamble notes that states can use information from private accreditation within the previous three years in lieu of mandatory EQR activities.[68] 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.[69] 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, CMS 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 instead to make the time lag worse.[70]

The example of nonduplication described in the preamble raises additional concerns about how the state will apply the "substantially comparable" standard.[71] HHS suggests that an MCO, PIHP or PAHP with NCQA accreditation must have undergone a

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[66] 68 Fed. Reg. 3603.
[67] *Id.*
[68] 80 Fed Reg. 31157.
[69] For example, in March 2014, Texas posted its *EQRO Summary of Activities and Trends in Healthcare Quality* – for contract year 2012. The Medicaid and CHIP data analyzed in this report covered calendar years 2009 through the end of 2011. Instit. for Child Health Policy at the Univ. of Fla. ("ICHP"), *Texas Medicaid Managed Care and Children's Health Insurance Program: EQRO Summary of Activities and Trends in Healthcare Quality* (Mar. 2014), http://www.hhsc.state.tx.us/reports/2014/EQRO-Summary.pdf; *See also* HHS OIG, *External Quality Reviews in Medicaid Managed Care*, 12 (June 2008), https://oig.hhs.gov/oei/reports/oei-01-06-00510.pdf.
[70] 80 Fed. Reg. 311282 [proposed § 438.364(b)].
[71] 80 Fed. Reg. 31156-57.

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 or any other non-HEDIS measures, in its managed care contracts, the state should still be responsible for contracting with an EQRO to separately validate all the non-HEDIS measures it requires. If accreditation standards are hidden behind a paywall or a claim of "proprietary property," stakeholders will have little 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, CMS has identified at least one "approved HEDIS auditor" that is paid by the MCO, and so, according to CMS, it is not "independent" under § 438.354.[72] While we agree with CMS 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 significant 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.

[72] CMS, *Responses to Comments Received after Federal Register Notice on Revised External Quality Review Protocols*, 3 (2012), available at http://www.reginfo.gov/public/do/DownloadDocument?documentID=328960&version=1.

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 CMS 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: **1.** 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.

2. Add language to paragraph (b)(2) to require states to create and maintain an archive of annual technical reports on its website, as follows:

> (2)…The State must make the most recent copy of the annual EQR technical report publicly available on the State's Web site required under § 438.10(c)(3) ***and maintain on such Web site an archive of all prior EQR technical reports published within the last five years.***

§ 438.370 - Federal Financial Participation

In the preamble, HHS explains that it has reviewed the statutory language relating to enhanced federal matching rates for the EQR and EQR-related activities. Specifically,

HHS is reinterpreting the statute to limit the enhanced 75% federal match to EQR activities for MCOs.[73] If finalized as proposed, EQR of PIHPs, PAHPs, and PCCM entities will only be eligible for the standard 50% administrative matching rate. The implications of this policy change for EQR are substantial. States with extensive PIHP programs, like California's county-based 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 § 438.354 for non-MCO entities. As written, 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's 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 § 1396a(a)(4) 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 EQR 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% federal match for EQR and EQR-related activities of PIHPs and extend the availability of that enhanced match to PAHPs and PCCM entities.

[73] 80 Fed. Reg. 31157-58.

SUBPART F - Grievance System

We strongly support HHS's efforts to update the Medicaid managed care grievance and appeal regulations. Over the years, Medicaid beneficiaries have repeatedly experienced improper disruptions in medically necessary care. The problem has moved front and center in our work because increasing numbers of people, including individuals with disabling and chronic conditions, are being enrolled in Medicaid managed care plans that use coverage procedures that are confusing to enrollees, that take too long for enrollees to use, and that incorporate utilization control mechanisms that terminate services without appeal rights even though the enrollee's health condition persists. Further complicating the situation, many of our clients have seen their managed care plans establish shorter periods of authorization for approved services. These limited periods appear to be arbitrarily set because they are not based on how long most of the people needing the service will need it or on how long the particular individual is expected to need the service. We have 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 received the service; State employees have told them to forego or dismiss their complaint became the case became moot when the authorization period ended before the date of the hearing.

Federal regulations have not kept pace with the reality. When the current regulations were promulgated in 2002, managed care was focused on primary and acute care for families and children, not chronic and long term care for aged, blind and disabled populations. In spite of this evolution in enrollment, the controlling legal precedent has remained the same. Then, as now, the law requires Medicaid administrative procedures (whether implemented by the single State agency or an entity contracting with the State) to reflect the legal rights guaranteed to Medicaid beneficiaries by the Due Process Clause of the U.S. Constitution as interpreted by *Goldberg v. Kelly,* 397 U.S. 254 (1970). The Due Process Clause guarantees that Medicaid beneficiaries must receive certain protections whenever benefits are reduced or terminated. Due process includes: (1) a meaningful, prior written notice of the decision to reduce or terminate, (2) the opportunity to receive a fair hearing before an impartial decision maker to challenge the decision, (3) aid paid pending, or continued benefits pending the outcome of the hearing, (4) a hearing decision based solely on the legal rules and evidence adduced at the hearing, and (5) a timely decision measured from the date the complaint is first made. *Id.* at 267- 71. Additionally, where people with disabilities are affected, health plans' administrative processes must account for the legal protections contained in the Americans with Disabilities Act, 42 U.S.C. §12131 *et seq.,* and implementing regulations.

The proposed regulations make significant strides toward bringing managed care grievance systems into the 21st century, even as they honor the age-old 20th century concept of Due Process. These regulations include provisions that recognize that the requirements of Due Process are not an ancillary responsibility of Medicaid managed

care programs, but are integral to the care management and care coordination functions of such programs. We agree with many of the changes that CMS is proposing.

That said, we do have concerns. 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 makes some aspects of the Medicaid grievance and appeal process unique and impossible to align. Thus, when called for, the regulations need to acknowledge how Medicaid is *different*. Moreover, while our comments and recommendations, below, focus upon subpart F, it is also true that subpart E of Part 431 (fair hearings for applicants and beneficiaries) has not kept pace with the reality. Thus, where appropriate in these subpart F recommendations, we will make some recommendations to update provisions of subpart E so that the two subparts are consistent with one another.

a. Subpart F - Grievance System

Uniform nomenclature should streamline and simplify the use of the grievance and appeal system. However, we are concerned that the subpart's title is going to be confusing. Subpart F is titled "Grievance System." "Grievance" is then defined to mean matters other than adverse benefit determinations, and "grievance system" is defined as the process for handling appeals of adverse benefit determinations and grievances (which the reader later learns are not appealable). Thus we recommend changing the title of this Subpart.

RECOMMENDATION*:* Amend the title of the Subpart to read:

Subpart F-Grievance **and Appeal** System

b. §438.400 - Statutory basis and definitions.

We recommend that CMS explicitly acknowledge that its authority to promulgate the regulations is controlled by the Due Process Clause of the Constitution. In addition to recognizing the overarching legal underpinnings that govern single State agencies and their contractors, this change will reduce confusion at the state/plan levels about what laws govern.

In addition, we are concerned that the phrase "adverse benefit determination," could be misleading to enrollees because it does not reflect the full range of actions that the health plan can take on the individual's claim for medical assistance under 42 U.S.C. § 1396a(a)(3) and *Goldberg*. This includes, for example, situations where requests for disenrollment or family member providers are denied by the plan. We suggest using the phrase "adverse coverage determinations."

We agree with the proposed definition for adverse benefit [coverage] determinations, with some amendment. Low-income enrollees can have health conditions that cannot be handled by their plan or their plan may stop providing services they need (as has happened with health plans that affiliate with Catholic hospitals and restrict access to contraceptive services). Confining beneficiaries to a plan that they cannot use is tantamount to denying them the services they need. Due process protections are needed to rectify these situations. *Accord Rosen v. Tenn. Comm'r of Fin. & Admin*., 280 F. Supp. 2d 743 (M.D. Tenn. 2002) (requiring adequate notice for persons with serious emotional disturbance or mental illness needed to include information about good cause exceptions). Similar due process concerns arise when a health plan denies an individual their choice of provider. *See*, *e.g*., *Hyden v. N.M. Human Servs. Dep't*, 16 P.3d 444 (N.M. Ct. App. 2000) (requiring due process when request for out-of-plan specialist refused by MCO).

The regulation also needs to better reflect the service delivery systems for long term services and supports. Many enrollees' services are determined through a budget setting process, and these budgets (where right or wrong) are sometimes used as a hard cap on the amount of services the enrollee can receive. As a result, the decision on the total budget is an action. *See LS v. Delia and Piedmont Behavioral Healthcare Authority*, No. 5:11-cv-354, 2012 U.S. Dist. LEXIS 43822 (E.D.N.C. Mar. 29, 2012) (holding plaintiffs likely to success on their claim that an action occurs when a budget is set), *aff'd sub nom*. *KC v. Shipman*, 716 F.2d 107 (4th Cir. 2013).

In addition, an adverse determination occurs when the amount of cost sharing is decided. This is particularly the case where services can be conditioned upon the payment of the cost sharing amount. The courts have long and repeatedly recognized the due process implications of cost sharing decisions, *e.g.*, *Becker v. Blum*, 464 F. Supp.152, 156-57 (S.D.N.Y. 1978) (requiring timely and adequate notice so recipients can determine if cost sharing provisions were applied correctly to them and be apprised of their rights to appeal); *Becker v. Toia*, 439 F.Supp.325 (S.D.N.Y. 1977). As HHS is aware, cost sharing is increasingly being imposed on low-income populations. The updated regulations should ensure enrollees have due process protections when their cost sharing is changed.

We also urge HHS to clarify that an adverse benefit determination includes a determination that there is not good cause for disenrollment. Section § 438.56(f) provides for access to the state fair hearing process. For clarity, HHS should add this to the list of reasons giving rise to a fair hearing. In addition, denial of request for exemption for enrollment should be added because such a decision has the same impact as a request for disenrollment.

Finally, provisions within subpart E of part 431should be amended to ensure that the health plan and state-level complaint resolution procedures are consistent and there is continuity when appropriate. Because PAHPs are now part of the 438.400 grievance and appeal procedures, this needs to be accounted for in the part 431 regulations.

Moreover, § 438.400(b) correctly recognizes that an adverse benefit determination occurs not only when a requested service is reduced, suspended or terminated but also when there is a denial or limited authorization of a requested service, *i.e.* less than the full amount of the service requested has been approved. The subpart E regulations are not consistent. It is absolutely critical that this inconsistency be addressed. (We suspect it was an oversight in drafting in the first place.) Medicaid enrollees, whether they are using managed care or FFS for their services, are seeking coverage for services. When those services are denied outright or the denial involves a portion of what was set forth in a request for prior authorization, the individual is not receiving the level of care that has been requested. This is not an academic concern. The District of Columbia Circuit Court of Appeals has just ruled, contrary to years of jurisprudence, that Medicaid enrollees did not have the right to a notice that requested services were being *denied* because 42 C.F.R. § 431.201 technically defines an "action" triggering notice to include only the "termination, suspension or reduction" of Medicaid eligibility or services. The opinion does recognize that that same individual has a right to a fair hearing to contest a denial (but says they do not have a right to a written notice of the denial which, of course, is what explains how to request a hearing). *See NB v. District of Columbia*, 2015 WL4385292 (D.C. Cir. July 17, 2015).

RECOMMENDATION: Amend subsection (a)'s listing of statutory basis as follows:

§ 438.400 ~~Statutory~~ **Legal** basis and definitions.

(a) *~~Statutory~~ Legal basis.* This subpart is based on sections 1902(a)(3), 1902(a)(4), and 1932(b)(4) of the Act

….

(4) ***The grievance and appeal system must meet the due process standards set forth in Goldberg v. Kelly, 397 U.S. 254 (1970), and any additional standards specified in this subpart.***

RECOMMENDATION: Amend subsection (b)'s definitions as follows:

(b) *Definitions.*

*Adverse **coverage** determination means*

(1) The **full or partial** denial or limited authorization of a requested service

…

(5) ***Denial of disenrollment or enrollment exemption requests;***

(~~5~~**6**) The failure of an MCO**,** ~~or~~ PIHP**, or PAHP** to act within the timeframes provided in § 438.404(b)~~(1) and (b)(2) regarding the standard disposition of grievances and standard disposition and resolution of appeals~~; ~~or~~

(7) Denial of choice of provider or out-of-plan service requests;

(8) A decision on the total budget for enrollees' services;

(9) Determination of a cost sharing amount; or
(10) For a resident of a rural area….
….
Grievance means … Grievances may include, but are not limited to, the quality of ~~care or~~ services **or continuity of care** provided, **the number and type of providers in the network, the amount of time required to travel to a provider, failure to provide information as required by § 438.10,** and aspects of interpersonal relationships such as rudeness ….

RECOMMENDATION: Amend § 431.201 as follows:

Action means a termination, suspension, reduction**, full or partial denial, or limited authorization** of Medicaid eligibility or service.

RECOMMENDATION: Amend §§ 431.200(b), 431.220(a)(5)-(6), and 431.244(f) to include proper reference to PAHPs.

RECOMMENDATION: Amend § 431.220(a)(1) as follows:

…(1) Any applicant **or beneficiary** who requests it because his claim for services is denied or is not acted on with reasonable promptness.

RECOMMENDATION: Amend § 431.244(f) as follows:

(f) The agency must take final administrative action as follows:
(1) Ordinarily, within 90 days from the earlier of the following:
(i) The date the enrollee filed for **an evidentiary hearing at the local level, if required by the State, or** ~~T~~ the date the fillee filed an MCO**, PAHP,** or PIHP appeal, ….

§ 438.402 - General requirements.

a. Exhaustion

CMS has requested comment on its proposal to require enrollees to exhaust the plan level appeal procedures before gaining access to a State fair hearing. We do not agree with the proposal. Rather, we strongly believe that it would be a mistake to eliminate states' flexibility to decide whether to require their residents to exhaust the plan-level grievance and appeal system before requesting a State fair hearing. Without doubt,

there are instances where enrollees convince health plans to reverse initial decisions; however, the plan-level review is not an impartial review under the law:

> Because of the pecuniary incentives that MCOs have for denying, suspending, or terminating care under the [managed care] system . . . enrollees need strong due process protections to protect themselves from inappropriate denials of health care.

Daniels v. Wadley, 926 F. Supp. 1305 (M.D. Tenn. 1996). The strongest protection for enrollees is to allow them direct access to the State fair hearing.

Unlike Medicare beneficiaries, Medicaid enrollees are uniformly, by definition, unable to afford to purchase health insurance out of pocket. Enrollees with disabilities can face particular stress and disadvantage if they are required to go through multiple levels of review, particularly when the claim involves an initial denial.

Over the years, NHeLP has not fielded complaints about the process from either enrollees or states where exhaustion in not required (*e.g.*, California, District of Columbia, Florida, Idaho, Maryland, Michigan, Missouri, New Jersey, New York, Pennsylvania, Tennessee, Texas, Virginia, Wisconsin). By contrast, advocates in New Mexico are experiencing problems because exhaustion is now required, and MCOs are improperly labelling internal appeals (which are appealable to the State) as requests for grievances (which are not appealable). The new rule will result in upheaval in these states, requiring administrative changes at the health plan and state level and are simply uncalled for.

We understand that some large insurance companies might favor an exhaustion requirement on the grounds that they rely on the internal appeals process to make them aware of a problem. However, if the health plan is implementing benefit and coverage policies as it should, then appeals should be infrequent, and problems should not come onto the plan's radar only when a formal dispute is filed. Importantly, the MCO, PAHP, or PIHP can always decide to change its decision, right up to the point where the State fair hearing decision is issued.

Notably, the forced change would not result in alignment because, as the preamble points out, insurers in group markets and group health plans are not similarly limited. Finally, given the ongoing upheaval with timely decision-making in the Medicare program, we have serious concerns with using the Medicare experience as the model. *See*, *e.g.*, *Exley v. Burwell*, No. 3:14-cv-01230-JAM (D. Conn.) (Compl. Aug.26, 2014) (concerning long waits for administrative hearings (from 194 to 626 days) for individuals whose claims were denied at the first level of review and where statute requires ALJ to render a decision within 90 days of filing a request for a hearing).

The decision whether or not to require exhaustion should remain a matter that should continue to be left to the State and stakeholders in the State. Exhaustion is also

anticipated in § 438.408, and we have addressed this issue in our proposed changes to that section.

RECOMMENDATION: Amend § 438.402(b) as follows:

> (c) *Filing requirements.* (1) *Authority to file.* (i) An enrollee may file a grievance and an appeal with the MCO, PIHP, or PAHP **and may request a State fair hearing**.. ~~An enrollee may request a State fair hearing after receiving notice under § 438.408 that the adverse benefit determination is uphold.~~
> . . .
> (2) *Timing--…*
> **(iii) In a State that does not require exhaustion of MCO, PIHP and PAHP level appeals, the enrollee may request a State fair hearing.**

b. Accessibility

Section 438.404(a) requires written notices to be consistent with the requirements of 438.10, which includes subsection 438.10(d)(3)'s requirement that written notices accommodate individuals who have limited ability to read the English language and who have disabilities. Similarly, section 438.406(a) requires MCOs, PIHPs and PAHPs to give enrollees interpreter assistance and auxiliary aids during grievances and appeals. We appreciate these provisions but suggest that provisions need to clearly extend these protections through the entire appeal process up through the state-level fair hearing.

RECOMMENDATIONS: 1. Amend § 438.406(a) as follows:

> *General requirements*. In handling grievances and appeals, each MCO, PIHP, and PAHP must**, consistent with § 438.10(d)(3) and (4),** give enrollees ~~any~~ **all** reasonable assistance in completing forms**, participating in a grievance or appeal,** and taking other procedural steps….

2. Amend § 431.205 and adding a new subsection (e), as follows:

> § 431.205 Provision of **notice and** hearing system.
>
> The Medicaid agency must be responsible for maintaining a **notice and** hearing system….
> The **notice and** hearing system must meet the due process standards set forth in *Goldberg v. Kelly*…

The notice and hearing system must ensure the provision of auxiliary aids and services at no cost individuals living with disabilities in accordance with the Americans with Disabilities Act and section 504 of the Rehabilitation Act and ensure that the system is accessible to individuals who are limited English proficient through the provision of language services at no cost to the individual.

§ 438.404 - Timely and adequate notice of adverse coverage [benefit] determination.

The notice of appeal is the foundation of due process. The proposed regulations include vital provisions that should ensure that managed care notices are consistent with *Goldberg*'s requirements for meaningful notices. In particular, we support §438.404(b)(2)'s requirements for notifying the enrollee of the reason for the adverse determination. Managed care plans have repeatedly cited trade secret, licensing, and business protections as the grounds for refusing to disclosure their medical necessity and clinical guidelines standards to our clients. And while courts have pointed out that trade secrets cannot trump the disclosure requirements for publicly funded programs, *e.g.*, *Salazar v. District of Columbia*, 596 F. Supp. 2d 67 (D.C.D.C. 2009), *partial recon.*, 750 F. Supp. 2d 65 (D.C.D.C. 2010), the use of secret standards has persisted.

RECOMMENDATION: Correct a typographical error in 438.404 (b)(6):

(6) The enrollee's right to have benefits continues~~s~~ pending resolution…

§ 438.406 - Handling of grievances and appeals.

We support this proposed regulation. In particular, we note our support of § 438.406(b)(2)(iii) (requiring plans to take into account all comments, documents, and information submitted by the enrollee without regard to whether the information was previously submitted).

Grievance and appeals processes are to be developed and implemented in the best interests of recipients. Thus we suggest including a specific timeframe for plans to acknowledge receipt of grievances and appeals rather than leave the timing open.

RECOMMENDATION: Amend section (a) as follows:

(b) *Special requirements.* …
(1) Acknowledge receipt of each grievance and appeal ***within 3 calendar days***.
…
(2) Ensure that the individuals who make decisions on grievances and appeals are individuals—

…

(ii) Who, if deciding any of the following, are health care professionals who have the appropriate clinical expertise, as determined by the State, in treating the enrollee's ***specific*** condition or disease ***and the specific services requested by the enrollee*.**

Further, § 438.404(a) requires written notices to be consistent with the requirements of 438.10, which includes subsection 438.10(d)(3)'s requirement that written notices accommodate individuals who have limited ability to read the English language and who have disabilities. Similarly, § 438.406(a) requires MCOs, PIHPs and PAHPs to give enrollees interpreter assistance and auxiliary aids during grievances and appeals. We appreciate these provisions but suggest that provisions need to clearly extend these protections through the entire appeal process up through the state-level fair hearing.

RECOMMENDATION: Amend § 438.406(a) as follows:

(a) *General requirements*. In handling grievances and appeals, each MCO, PIHP, and PAHP must***, consistent with § 438.10(d)(3) and (4),*** give enrollees ~~any~~ ***all*** reasonable assistance in completing forms***, participating in a grievance or appeal,*** and taking other procedural steps….

§ 438.408 - Resolution and notification: Grievances and appeals.

We agree with the quantified timeframes that are incorporated into the proposed regulations. However, we are concerned that the instructions for plans and the protections for enrollees need to be more specific when it comes to expedited appeals. For example, enrollees' expedited appeals should not be cast over to the grievance process when a health plan decides to extend the timeframes, not at the request of the enrollee, and the enrollee disagrees with that decision. The need for an expedited appeal arises when enrollees are facing a critical, demanding health care problem. These individuals have qualified for Medicaid (as opposed to commercial insurance or Medicare) because they have low income and, thus, lack the alternative financial resources to pay for the care while they await a Medicaid decision.

As noted elsewhere in these comments, we do not agree with CMS's proposal to eliminate state flexibility to decide whether to require the plan-level grievance and appeal system to be exhausted. However, regardless of whether exhaustion is required, enrollees should be allowed access to the state fair hearing process to obtain a decision on their claim for medical assistance when the MCO, PIHP, or PAHP is not making decisions in a timely manner. Problems with timely administrative decisions are rampant in the states. It is certainly in enrollees' interests to move them through the system toward a final administrative decision and not allow them to become caught up in delays at the plan level.

We are also making a recommendation regarding parties at the state fair hearing. We have worked with advocates and enrollees in states where the state Medicaid agency is refusing to attend the fair hearing. This is unacceptable. The state Medicaid agency is the single state entity that is responsible for implementing Medicaid, including, ultimately, all fair hearing decisions. Moreover, there can be aspects of the hearing decision in an enrollee's favor that depend on state involvement. When the state refuses to attend the hearing, this causes needless delay and is clearly not in the enrollee's best interest.

RECOMMENDATION: Amend § 438.408 as follows:

(b) *Specific timeframes*.

(1) *Standard disposition of grievances.* For standard disposition of a grievance and notice to the affected parties, the timeframe is established by the State but may not exceed ~~90~~ **30** days from the day the MCO, PIHP, or PAHP receives the grievance.

….

(c) *Extension of timeframes*.

(1) The MCO, PIHP, or PAHP may extend the timeframes from paragraph (b) of this section by up to 14 calendar days, ***or 72 hours in the case of an expedited appeal***, if—

(i) The enrollee requests the extension; or

(ii) ***Only in the case of a standard resolution under (b)(2)*****,** the MCO**,** PIHP, or PAHP shows (to the satisfaction of the State agency, upon its request) that there is need for additional information and how the delay is in the enrollee's interest. ***In the case of an expedited appeal under (b)(3), the MCO, PIHP, or PAHP must show (to the satisfaction of the State agency) that there is need for additional information and that the delay is in the enrollee's interest and will not jeopardize the enrollees' life or health or ability to attain, maintain or regain maximum functions.***

(2) *Requirements following extension.* If the MCO, PIHP, or PAHP extends the timeframes, not at the request of the enrollee, it must complete all of the following:

(i) Make reasonable efforts to give the enrollee prompt***, same day*** oral notice of the delay.

(ii) Within 2 calendar days, ***in the case of a standard resolution under (b)(2), and within 24 hours, in the case of an expedited***

appeal under (b)(3), give the enrollee written notice of the reason for the decision to extend the timeframe and inform the enrollee of the right to file a grievance if he or she disagrees with that decision ***and, for expedited appeals, make a decision on the grievance within 24 hours*.**

(d) When a standard or expedited resolution of appeals not reached within the timeframes set forth in this section, this constitutes an adverse coverage determination on the service authorization decision as of the date the timeframe expires. The enrollee must be informed of the right to request a State fair hearing to contest the service authorization decision as set forth in §438.408(2).

(~~d~~***e***) *Format of notice*. (1) *Grievances.* The State must establish the method that an MCO, PIHP, and PAHP will use to notify an enrollee ***in writing*** of the disposition….

(2) *Appeals.*

….

(ii) For notice of an expedited resolution, the MCO, PIHP, or PAHP must also make reasonable efforts to provide oral notice ***within 24 hours. The MCO, PIHP, and PAHP must issue a written notice no later than 2 calendar days after the disposition***.

…

(~~e~~***f***) *Content of notice of appeal resolution.*

…

(~~f~~***g***) *Requirements for State fair hearings*.

…

~~(1) *Availability.* An enrollee may request a State fair hearing only after receiving notice that the MCO, PIHP or PAHP is upholding the adverse benefit determination.~~

(2) The enrollee must request a State fair hearing no later than 120 calendar days ~~from the date of the MCO's, PIHP's, or PAHP's notice of resolution~~ whichever of the following dates applies

(i) If the State requires exhaustion of the MCO, PAHP or PIHP level appeal procedures, from the date of the MCO's, PAHP's, or PIHP's notice of resolution; or

(ii) If the State does not require exhaustion of the MCO,PAHP, or PIHP level appeal procedures and the enrollee appeals directly to the State for a fair hearing, from the date on the MCO's, PAHP's, or PIHP's notice.

~~i.~~

(3) *Parties.* The parties to the State fair hearing include the MCO***, PAHP***, or PIHP; ***the single state Medicaid agency,*** as well as the enrollee and

his or her representative or the representative of a deceased enrollee's estate.

§ 438.410 - Expedited resolution of appeals.

The grounds for granting an expedited appeal should be stated in the regulation as clearly as possible.

RECOMMENDATION: Amend subsection (a) to state:

(a) *General rule*. … standard resolution could seriously jeopardize the enrollee's life or ***physical or mental*** health or ability to attain, maintain, or regain maximum function.

§ 438.414 - Information about the grievance system to providers and subcontractors

As discussed above, we are suggesting that grievance and appeal references in subpart F be clarified so that they are not confusing.

RECOMMENDATION: Amend this provision as follows:

The MCO, PIHP, or PAHP must provide information specified in § 438.10(g)(2)(ix) about the grievance ***and appeal*** system to all providers and subcontractors at the time they enter into a contract.

§ 438.416 - Recordkeeping requirements.

Health plans should be required to keep records on how well the process grievances and appeals. Poorly performing plans should improve under corrective action plans or be terminated from participating in Medicaid.

RECOMMENDATION: Add a new subsection (d) to § 438.416 as follows:

(d) The State must also require the MCOs, PIHPs, and PAHPs to maintain records, on a quarterly basis, of the total number of grievances and of the total number of appeals, and for appeals:
(i) the number of times the standard timeframe for resolution was extended, not at the request of the enrollee;
(ii) the number of times the expedited timeframe for resolution was extended, not at the request of the enrollee; and
(iii) the number of timeframes specified in § 438.210(d) were not met.

§ 438.420 - Continuation of benefits while the MCO, PAHPs, or PIHP appeal and the State fair hearing are pending.

The National Health Law Program and advocates with whom we work nationwide heartily thank CMS for promulgating this regulation. Consistent with the requirements for constitutional due process, this regulation is designed to allow an enrollee to maintain the previously authorized level of benefits uninterrupted pending the State fair hearing decision—including during the pendency of the plan level appeal. Indeed, the related concept of an "authorization period," addressed in 42 C.F.R. § 438.420, is one that must be crafted specially to protect the due process rights of Medicaid enrollees. Under *Goldberg*, they have the poverty-driven, "brutal need" for continued benefits pending appeal that rises to the level of a constitutional protection. Moreover, as HHS has recognized, Medicaid managed care plans now cover LTSS, behavioral health care, and other ongoing services for long-term chronic conditions. Due process requires that an enrollee be guaranteed continuation of these services regardless of whether a utilization control system's "authorization period" has expired.

We greatly appreciate the preamble's clear statement of HHS' intent to ensure that needed services are not interrupted based on application of "authorization periods." Nevertheless, this aspect of the grievance and appeals proposed regulations has, without question, generated the most discussion among legal advocates for Medicaid beneficiaries during the comment period. The concern is rooted in the fact that it is the wording of the regulation that will control, not the preamble or webinar statements. Moreover, the proposed regulation § 438.420 defines "timely appeal" but then does not use the term in the remainder of the rule. We are suggesting small clarifications to address possible confusion about the requirements for continued benefits. Our suggestions for amending § 438.420 should be read in tandem with our suggestions for amending § 438 210, Continuation and authorization of services.

We also strongly support the amendments made to clarify requirements for recoupment but are recommending some additional protections for people with disabilities and limited English proficiency.

RECOMMENDATION: Amend § 438.420 as follows

(a) *Definitions.* As used in this section—

Timely fil~~ing~~***es*** means filing on or before the later of the following—

(i) ~~Within 10 calendar days of the MCO, PIHP, or PAHP mailing the notice of adverse benefit determination.~~ ***Before the date the adverse coverage determination is to take effect. (The MCO, PIHP, PAHP must mail an advance notice as required by § 438.404(c)(1)).***

(b) *Continuation of benefits.* The MCO, PIHP, or PAHP must continue the enrollee's benefits if all of the following occur: …

(1) The enrollee or the provider ***timely files*** ~~files the appeal timely~~;

(2) The appeal involves the termination, suspension, or reduction of a previously authorized course of treatment **or services**;

(3) The **course of treatment** or services were ordered by an authorized provider; **and**

~~(4) The original period covered by the original authorization has not expired; and~~

(~~4~~5) The enrollee **or provider** request**s** extension of benefits **under § 438.210(b)(3)**.

We also support the amendments made to clarify requirements for recoupment but are recommending some additional protections for people with disabilities and limited English proficiency.

RECOMMENDATION: Amend § 438.420 as follows:

(d) *Enrollee responsibility for services furnished while the appeal is pending.* … Such practices must be consistently applied within the State under managed care and FFS delivery systems. **To recover costs from an enrollee who has LEP or has a disability that requires information provided in alternate formats, the MCO, PIHP**, **or PAHP may only recover the cost of the services furnished to the enrollee while the MCO, PIHP or PAHP appeal and State fair hearing are pending if the MCO, PIHP, or PAHP can document that it provided the enrollee with information about recovery in the enrollee's language or in an alternate format to meet the needs of an individual with a disability.**

***New* § 431.234 - De novo State fair hearing**

Under *Goldberg*, a constitutionally impartial hearing will not occur until the individual reached the state fair hearing level of appeal. See, e.g., *Daniels v. Wadley,* 926 F. Supp. 1305 (M.D. Tenn. 1996). To ensure this fairness, the state fair hearing needs to occur de novo. We thus make the following recommendations.

RECOMMENDATION: Add a new provision, 42 C.F.R. § 431.234, as follows:

§ 431.234 State agency hearing after adverse decision of MCO, PIHP, or PAHP

(a) Unless the enrollee specifically requests a review by the agency hearing officer of the record of the MCO, PIHP or PAHP decision to determine

whether the decision was supported by substantial evidence in the record, the State agency hearing shall consist of a de novo hearing.

(b) If the hearing involves the termination, reduction or suspension of a previously approved service, the MCO, PIHP or PAHP will have the burden of proof. If the hearing involves the initial request for a service, the enrollee will have the burden of proof.

§ 438.424 - Effectuation of reversed appeal resolutions.

We agree with the proposed regulation's requirement that health plans promptly deliver services that are awarded on appeal but were not furnished while the appeal was pending. We are concerned that the proposal is worded in a way that will not achieve this goal. It is not enough for the health plan to simply authorize the withheld service.

RECOMMENDATION: Amend subsection (a) to read:

> (a) *Services not furnished while the appeal is pending.* If the MCO, PIHP, or PAHP***,*** ~~or~~ the State fair hearing officer***, or a final court decision*** reverse***s*** a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the MCO***,*** ~~or~~ PIHP***, or PAHP*** must ~~authorize or provide~~ ***ensure*** the disputed services ***are provided to the enrollee*** promptly, and as expeditiously as the enrollee's ….

NATIONAL HEALTH LAW PROGRAM

SUBPART H - Additional Program Integrity Safeguards

§ 438.602 - State responsibilities.

We commend HHS for significantly strengthening oversight, accountability, and transparency in Medicaid managed care. We strongly support requiring periodic, independent audits of encounter data and financial data. Independent auditing and performance reviews provide critical information and identify program deficiencies that may not otherwise be detected. Over-reliance on minimum, selected performance measures and narrowly focused EQR may provide a skewed image of plan performance. Auditing and transparency requirements provide an effective check on the tendency of plans to "teach to the test." Healthcare advocates and policy makers have long observed that "what gets measured gets done."

Accordingly, we recommend HHS expand independent auditing requirements beyond encounter and financial data to include other program requirements, including provider networks, timely access standards, care coordination, language access and access for individuals with disabilities, utilization management, access to family planning services and referrals, and the grievance, appeals, and exceptions process, among others.

We also recommend that the results of audits, as well as contracts, MLR compliance, and other data be publicly posted to the state website, and not simply be made available up on request. Under the current Medicaid managed care rules, EQR technical reports must be provided upon request, with no public posting requirement. Some states have proven reluctant to provide the reports, and some advocates and other stakeholders are unaware that such reports even exist.

Posting documents on a public website does not create an undue burden for states. For full transparency, public posting of important information on public programs should be a requirement, and not optional for states.

We also urge HHS to make these requirements applicable to PCCM entities.

RECOMMENDATION: Amend subsections (e) and (g) as follows:

> (e) Periodic audits. The State must periodically, but no less frequently than once every 3 years, conduct, or contract for the conduct of, an independent audit of the accuracy, truthfulness, and completeness of the encounter and financial data submitted by, or on behalf of, each MCO, PIHP ~~or~~ PAHP, ***or PCCM entity***. ***The State must also conduct, or contract for the conduct of, periodic, independent audits of other aspects of its managed care program, including provider networks, timely access standards, care coordination, language access and access for individuals with disabilities, utilization management, access to family planning services and referrals, and the***

grievance, appeals, and exceptions process those subject to State monitoring under § 438.66.

(g) Transparency. The State must post on its Web site ~~or make available upon request~~ the following documents and reports: . . .

SUBPART J - Conditions for Financial Participation

§ 438.807 - Deferral and/or disallowance of FFP for non-compliance with Federal requirements

We generally supports HHS's proposed interpretation of § 1902(m)(2)(A) to allow for partial deferrals and/or disallowances of FFP for non-compliance. We believe that this "service by service" interpretation provides penalty that HHS is more likely to use. Targeted deferrals and disallowances may also be less likely to negatively impact enrollees and their access to health care services than the withholding of full federal financial participation. In addition, we support HHS's interpretation that targeted deferrals and/or disallowances may be applied to all services covered under the contract and not just inpatient services and other services listed in paragraphs (2), (3), (4), (5), or (7) of 1905(a). We do note, however, that the language in the preamble suggests that under the proposed interpretation HHS would no longer have the option to fully withhold FFP for non-compliance.[74] The potential to lose full FFP provides a greater incentive for states to ensure compliance. For this reason, we recommend clarification that HHS may pursue full or partial deferrals and disallowances for non-compliance, as is allowed for compliance problems with the administration of a state plan under section 1904.

§ 438.818 - Enrollee encounter data

We commend HHS for including section 438.818. We agree that "Medicaid programs need robust, timely, and accurate data to ensure the highest financial and program performance."[75] Since accurate, timely, and complete encounter data is so important, we urge HHS to specifically require not only that the encounter data provisions under section 438.242 apply to NEMT PAHPs, but also that the federal financial participation requirements under section 438.818 be applicable to NEMT PAHPs.

a. § 438.818(c)

This section raises questions as to when a deferral will be pursued and when a disallowance will be pursued. While §§ 430.40 and 430.42 clearly distinguish between when a deferral occurs and when a disallowance occurs, it is unclear how these distinctions will be incorporated into the situation described in § 438.818(c). Because of this confusion, we request that HHS provide greater clarity on when deferral is appropriate, when a disallowance is appropriate, and when either may be appropriate as they are applied to this subsection.

[74] *See* 80 Fed. Reg. 31132.
[75] *Id*. at 31166.

Part 457 - CHIP

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.

Subpart L - Managed Care

§ 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 § 4 57.1201(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 suggest incorporating our comments § 438.4(b)(7) in this section. We do suggest that HHS evaluate whether an 85% MLR is appropriate for CHIP.

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 recommend that HHS apply the recommendations we made for MLR in Medicaid to CHIP although HHS should evaluate whether an 85% threshold is appropriate for CHIP.

§ 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

We recommend incorporating our comments regarding § 438.10 and § 438.72 (proposed new section) here as well.

§ 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 to determine how to best achieve the alignment and modernization goals of this regulation.

§ 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 recommend incorporating our comments regarding § 438.68 in this section as well.

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.

We also recommend including our comments related to the Medicaid beneficiary support system in § 438.71 in this section as well.

§ 457.1224 - Marketing Activities

We support aligning the marketing activities with Medicaid at § 457.1224 by cross reference to § 438.104. We suggest incorporating our comments related to § 438.104 in this section as well.

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.

§ 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 believe should be reflected in CHIP as well.

We 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.
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.

§ 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 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 should be incorporated here as well.

§ 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 in §§ 438.310-438.340 which we suggest incorporating in this section as well.

§ 457.1250 - External Quality Review

We suggest incorporating our comments on the EQR sections in Medicaid in this section.

§ 457.1260 - Grievance system

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.

§ 457.1280, .1285 - 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 suggest incorporating here as well.