



**CONSORTIUM FOR CITIZENS
WITH DISABILITIES**

July 27, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-2390-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Delivered Electronically

Ref: CMS-2390-P Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability

Dear Acting Administrator Slavitt:

The Consortium for Citizens with Disabilities Health and Long Term Services and Supports Task Forces (hereafter referred to as CCD) appreciates the opportunity to provide comments on the proposed managed care rule. CCD is a coalition of national disability organizations working together to advocate for national public policy that ensures the self-determination, independence, empowerment, integration and inclusion of children and adults with disabilities in all aspects of society.

CCD appreciates CMS's effort to align Medicaid managed care rules with the rules for Medicare Advantage (MA) and private health insurance sold on the Marketplace, and to update its regulations to take into account the increasing coverage of long-term services and supports (LTSS) for people with disabilities, older adults, and children and adults with special health care needs through Medicaid managed care. Because LTSS services have not been a significant part of MA or the private insurance system, aligning Medicaid managed care rules with the rules for these systems presents some challenges. While it is clear that CMS has given serious thought to how to address these issues, there are a number of places where we think the rule should be more specific to ensure that the needs of beneficiaries with disabilities or special health care needs, and those receiving LTSS services are adequately met.

The following pages provide comments on the specific sections of the rule and highlights are suggested language changes in bold and italics.

Subpart A General Provisions

§ 438.2 Definitions

Long-Term Services and Supports (LTSS)

CCD supports CMS's proposed definition for long-term service supports (LTSS), but recommends that the definition be expanded to reflect the broad scope of LTSS, and to at least include non-residential settings. We suggest the following changes to reflect the existence of workplaces and provider-owned or controlled non-residential settings.

Recommendation:

Long term services and supports means services and supports provided to or on behalf of beneficiaries of all ages who have functional limitations and/or chronic illnesses that have the primary purpose of supporting the ability of the beneficiary to live or work in the setting of their choice, which may include the individual's home **or workplace**, a provider-owned or controlled ~~residential~~ setting, a nursing facility, or other institutional setting.

Habilitation Services and Rehabilitation Services and Devices

CCD supports § 438.10(c)(4)(i) that the state must develop standard definitions of terminology. We request that CMS change the reference of "habilitation services" to "habilitation services **and devices**" and "rehabilitation services" to "rehabilitation services **and devices**" to be consistent with CMS' final rule *Patient Protection and Affordable Care Act; CMS Notice of Benefit and Payment Parameters for 2016* and to make clear to enrollees that both services and devices are covered habilitative and rehabilitative benefits¹

We recommend that CMS add robust definitions for habilitative and rehabilitative services and devices into § 438.2. We recommend the following definitions:

Rehabilitation Services and Devices: Includes but is not limited to health care services and devices that are designed to assist individuals in improving or maintaining, partially or fully, skills and functioning for daily living. These services include, but are not limited to, physical therapy, occupational therapy, speech-language pathology and audiology, cognitive rehabilitation, and psychiatric rehabilitation services in a variety of inpatient and/or outpatient settings.

Rehabilitation devices shall include, but not be limited to, orthotics and prosthetics, prosthetic devices, low-vision aids, Augmentative and Alternative Communication Devices (AACs), and hearing aids and assistive listening devices, as defined elsewhere in this section. Rehabilitative services should be provided based on the individual's needs, in consultation with a clinician, and based on an assessment by an interdisciplinary team and resulting care plan.

¹ *Patient Protection and Affordable Care Act; CMS Notice of Benefit and Payment Parameters for 2016*, Vol. 79, No. 228 of the *Federal Register*, at p. 70717, published on November 26, 2014.

Habilitation Services and Devices: Includes but is not limited to health care services and devices that are designed to assist individuals in acquiring, improving, or maintaining, partially or fully, skills and functioning for daily living. These services may include, but are not limited to, physical therapy, occupational therapy, speech-language pathology and audiology, and other services and devices for people with disabilities in a variety of inpatient and/or outpatient settings. Plans should use Medicaid coverage as a guide where there is a question of whether to cover specific habilitation benefits.

Habilitation services should be provided based on the individual's needs, in consultation with a clinician, and based on an assessment by an interdisciplinary team and resulting care plan. Habilitation devices shall include, but not be limited to, orthotics and prosthetics, prosthetic devices, low-vision aids, Augmentative and Alternative Communication Devices (AACs), and hearing aids and assistive listening devices, as defined elsewhere in this section.

We urge CMS, at the very least, to include the National Association of Insurance Commissioners' (NAIC) definitions for these health service categories to this section to provide clarity and uniformity to the habilitative and rehabilitative services and devices provided through Medicaid managed care.² CCD has previously submitted comments to CMS in response to the Secretary of Health and Human Services' *Essential Health Benefits Bulletin*³ and in response to notices of proposed rulemakings for the standards to govern states health exchanges' essential health benefits (EHB). Each time that we have commented, we have urged CMS to apply the NAIC's definitions of "rehabilitation services" and "habilitation services" to all state health exchanges' QHPs. Adopting this definition across QHPs, MCOs, PAHPs, and PHIPs would advance CMS's goal of alignment between programs.

Durable Medical Equipment

CCD also proposes that "durable medical equipment" should be included in § 438.2, with the following definition:

Durable Medical Equipment: Includes but is not limited to equipment and supplies ordered by a health care professional for everyday or extended use to improve, maintain or prevent the deterioration of an individual's functional ability. Examples of DME include, but are not limited to, manual and power wheelchairs, oxygen equipment, canes,

² The National Association of Insurance Commissioners (NAIC) defines "Habilitation Services" as "Health care services that help a person keep, learn or improve skills and functioning for daily living." NAIC defines "Rehabilitation Services" as "Health care services that help a person keep, get back or improve skills and functioning for daily living that have been lost or impaired because a person was sick, hurt or disabled."

See NAIC's Glossary of Health Insurance and Medical Terms at

http://www.naic.org/documents/committees_b_consumer_information_ppaca_glossary.pdf.

³ The Secretary of the Department of Health and Human Services issued an *Essential Health Benefits Bulletin* on December 16, 2011 through the Center for Consumer Information and Insurance Oversight (CCIIO). The *Bulletin* provided states with federal guidance for the selection of their benchmark state exchange health plan and design of essential health benefits (EHB). The *Bulletin* can be accessed at

https://www.cms.gov/CCIIO/Resources/Files/Downloads/essential_health_benefits_bulletin.pdf.

crutches, walkers, standing system chairs, blood testing supplies for people with diabetes, as well as supplies, equipment, and repairs to support medically necessary devices.

Orthotics and Prosthetics

CCD finally proposes that “orthotics and prosthetics” should be included in § 438.2, with the following definition:

Orthotics and Prosthetics: Leg, arm, back, and neck braces, and artificial legs, arms, and eyes, and external breast prostheses incident to mastectomy resulting from breast cancer. These services include: adjustments, repairs, and replacements required because of breakage, wear, loss, or a change in the patient’s size or physical condition.

§ 438.3 – Standard contract requirements

Antidiscrimination

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

We enthusiastically support the decision to add disability as a protected category in §438.3(d)(4). 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 provision of services, 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 enrollees with disabilities who have high service needs or are difficult to deal with are treated poorly by managed care entities in an effort to get such individuals to switch managed care entities.

Long-Term Service and Supports

CCD supports efforts of CMS to align managed care rules with the regulations for settings of home and community-based services at § 441.301(c)(4). CCD understands § 438.3(o) of the proposed rule to mean that MCOs, PIHPs, and PAHPs must meet the settings requirements in § 441.301(c)(4), including when provided under 1115, 1915(b), or other managed care or LTSS financing mechanism. CCD is supportive of this explanation of LTSS contract requirements, and urges CMS to provide information on the enforcement measures that will be taken to ensure that plans follow the HCBS settings rule in their contracts. CCD suggests that one way to accomplish this is to add a requirement to monitor plan compliance with § 441.301(c)(4) onto § 438.66(b)(13).

CCD supports the requirement in § 438.208(c)(3)(ii) that the LTSS treatment plan be developed by a person trained in person centered planning. CCD requests more clarity in the rule to explain that

the definition of the person-centered process and planning is the same as the one provided in §441.308(c)(1) and (2).

We support the addition of LTSS contract requirements at (o), but urge CMS to include explicit reference to the *Olmstead v. LC* decision as suggested below (changes in bold and underlined). *Olmstead*'s requirements, including the integration mandate, apply to all programs, services and activities of state and local government entities, including the delivery of Medicaid services through managed care contracts. As CMS has stated, "All MLTSS programs must be implemented consistent with the Americans with Disabilities Act (ADA) and the Supreme Court's *Olmstead v. L.C.* decision. . . . States must require MCOs to offer services in the most integrated setting possible." CMS, *Guidance to States using 1115 Demonstrations or 1915(b) Waivers for Managed Long-Term Services and Supports Programs*, at 8 (May 20, 2013).

Managed care entities whose prior experience has been primarily or exclusively in the private market have little or no experience implementing the *Olmstead* decision. Accordingly, it is particularly important that the requirement to comply with *Olmstead* be an explicit part of managed care contracts so that managed care entities are fully aware of it.

§ 438.3(o) *LTSS contract requirements*. Any contract with an MCO, PIHP or PAHP that includes LTSS as a covered benefit must require that any services covered under the contract that could be authorized through a waiver under section 1915(c) of the Act or a State plan amendment authorized through sections 1915(i) or 1915(k) of the Act be delivered in settings consistent with § 441.301(c)(4) of this chapter. ***All contracts must also require that services be provided in compliance with ADA's integration mandate and Olmstead v. L.C.***

438.3 (s) Prescription Drug Formulary Requirements

In states that require MCOs to provide drug benefits, CMS is proposing to require MCOs to provide drug coverage that "meets the standards . . . imposed by [the Medicaid rebate statute, section 1927 of the Social Security Act] as if such standards applied directly to the MCO." However, the proposed rule allows states to permit MCOs to maintain their "own formularies" without specifying that those formularies must comply with the formulary requirements in Section 1927. CMS does state in the Preamble that plan enrollees must be able to access non-formulary medicines through prior authorization "when there is a medical need."

In order to maximize access to all clinically appropriate medications, CCD recommends that CMS clarify that MCO formularies must satisfy all applicable formulary rules in Section 1927, and clarify enrollee rights to obtain an off-formulary medication. CMS should further address the process for obtaining off-formulary medications in ways that are simple for both the enrollee and their prescribing physician. Given the importance of broad access to full array of medications for Medicaid beneficiaries, CMS should add clear protections for non-formulary medicines to the regulatory text. Without clear regulatory protections and enforcement of these rules, it is doubtful that plan enrollees will be able to fully benefit from Section 1927's protections. This is of particular concern to CCD given the given the recent history of Medicaid fee-for-service programs that are governed by Section 1927. In recent years, our member organizations have witnessed

significant restrictions on access to medications years including severely restrictive preferred drug lists (PDLs) and imposition of policies such as step therapy, prior authorization and “fail first” requirements.

§ 438.10 – Information Requirements

We acknowledge and support CMS’s direction to states and MCOs to meet the effective communication needs of individuals with disabilities and Limited-English Proficiency (LEP), and we particularly applaud the agency’s ground-breaking recognition of the need for accessibility information in MCO provider directories. At the same time, we have a number of recommendations for the Information Standards section that we believe will help focus state and MCO efforts on meeting the overall accessibility presented in this section.

(a) Definitions – readily accessible

If the proposed rule seeks to establish the term “readily accessible” as a term that describes accessible information, we recommend that the term be broadened to apply to information provided in any form. Currently, the definition appears to be limited to electronic information and services, while such phrases as “written materials must also be made available in alternative formats” and “auxiliary aids and services are available upon requests and at no cost for enrollees with disabilities” are scattered throughout §438.10 to specify state and MCO requirements under Section 504 and Title II and III of the ADA. This will potentially result in inconsistent misreading of state and plan obligations to provide effective communication, and the false assumption that people with disabilities have varied rights to different formats depending on the covered entity’s choice to provide particular formats in the first place. For example, the first basic rule under §438.10(c) states that all required information in the section must be provided in a manner and format that is “readily accessible,” but the current definition appears to apply only to electronic information.

Our recommendation is for one broad definition of readily accessible that encapsulates the effective communication obligations of states and Medicaid MCOs under Section 504 and the ADA. We recommend amending § 438.10 (a) as follows:

Readily accessible means compliance with effective communication obligations, free of charge and upon the request of a person with a disability, in accordance with federal accessibility laws. Readily accessible includes the use of accessible electronic methods that comply with Section 508 Guidelines or Web Content Accessibility Guidelines (WCAG 2.0 AA) that provide greater accessibility to individuals with disabilities, the timely provision of auxiliary aids and services, and the delivery of information through alternative formats within five calendar days of an original request or concurrently with the delivery of printed formats, giving primary consideration to the request of the individual with a disability unless meeting the request would result in an undue burden or a fundamental alteration of the program or service.

This definition, when applied throughout § 438.10, will help MCOs to understand and consistently meet their accessibility obligations, and apply those obligations in conjunction with the information requirements under proposed rule. Our definition establishes that:

- The alternative format choice of the person with a disability takes precedence over the state's choice in § 438.10(e) to provide potential enrollees with specified information in either paper or electronic form. As currently written, a state could potentially assert that a choice to provide materials in an electronic form means that it can bypass the alternative format and auxiliary aids and services obligations that apply to "all written materials" under § 438.10(d). Under § 438.10(c)(6), electronic information provided by the state must also be electronically accessible, but § 438.10(c)(6)(v) only narrowly indicates that electronic information must also be available "in paper form" without charge and upon request, which arbitrarily excludes the possibility of audio formats.
- ADA/504 rights accrue to individuals with disabilities who interact with the plan, regardless of their official status as enrollees or potential enrollees; for example, the Deaf parents of a minor enrollee have a right to sign language interpretation when discussing their minor enrollee's health conditions, treatment options, and treatment authorizations with providers and plan representatives.
- States and MCOs need to establish policies and procedures to consider and respond to requests for reasonable accommodation and effective communication in accord with existing law, which gives priority to the preferred request of the individual with a disability.
- Requests for auxiliary aids and services and alternative formats need to be met in a timely manner, and all alternative format requests must be met within five calendar days. Currently the only timeliness obligation in the entire section appears to apply only to the state's obligation to provide a written format upon request when the state chooses to only provide information/materials in an electronic format: § 438.10(c)(6)(v).

Finally, we strongly urge CMS in this proposed rule to require states and MCOs to adopt data procedures and communication preference policies that will enable them to meet, on an *ongoing* basis, the alternative format/auxiliary aids and services request of individuals with disabilities once made. An enrollee who is blind, for example, should not bear the burden of having to be constantly alert to mailings she cannot independently see, just so she can make yet another request to receive the latest notice that she cannot identify or read in the same alternate format she has already previously requested. Moreover, even where a request has not been actively made, states and MCOs should deliberately reach out to potential enrollees and enrollees who *they know are blind* to ask them if they would like an alternate format. When the duals integration project in California was initiated, Medicare and Medicaid-eligible individuals received notices 90, 60, and 30 days ahead of their requisite passive enrollment date. Upon pressure from advocates, the state indicated that upon request, it would provide dually-eligible persons with this set of notices in their requested alternative format, but the state indicated that they would not carry through the alternate format request made by the individual to any other post-enrollment Medicaid managed notices or information. It is critical, when states and MCOs are already investing very substantial amounts

toward meeting health information technology goals, for these entities to proactively build in the technical and procedural capacity to meet the information needs of both individuals with disabilities and individuals with LEP.

§ 438.10(c)(4)(i) – Definitions for managed care terminology

We also urge CMS to include the following changes and additional terms that states must develop under § 438.10(c)(4)(i) for uniform adoption by MCOs.

- Behavioral health services - given the historical exclusion of mental health services by private insurance, failure to include such a definition creates the incorrect impression that such services are not covered.
- Continuity of care – this is a critical aspect of care for every Medicaid beneficiary with disabilities and plans must explicitly address beneficiary concerns on this front.
- Care coordination - these services should form the linchpin of managed care involvement in Medicaid service delivery and require uniform definition.
- The terms “Habilitation services” and “rehabilitation services” must be broadened to encompass devices as well as services. This is consistent with habilitation and rehabilitation terminology under the essential health benefits that QHPs must cover, and use of the same terminology meets CMS’ goal of aligning exchange and Medicaid coverage whenever possible.
- Health risk assessment – many Medicaid beneficiaries will be unfamiliar with this term and will benefit from a uniform foundational description of the concept.
- State’s with MCO, PIHP or PAHP contracts which also cover LTSS should be required to develop uniform definitions of adult day services, community-based providers, home and community-based services, in-home personal assistance, LTSS, *Olmstead v. L.C.*, non-emergency transportation, and any other critical components of Medicaid LTSS within the state.

States may also benefit from a clear direction to seek guidance from best practices within and outside of the state pertaining to Medicaid coverage, rather than managed care or private insurance coverage which has not historically covered the above benefits.

§ 438.10(c)(6)

We applaud the requirement that where states and MCOs provide enrollee information electronically and through their websites, they must ensure that the information is fully accessible. We also strongly support the specific requirement that electronic information must be electronic information is in a form that can be electronically retained and printed.

We recommend two additional clarifications in this section. First, there should be a direct requirement that the entire state or MCO website on which Medicaid enrollee information is placed be readily accessible, not just the enrollee information itself. Websites that have untagged pictures and illustrations, documents that are not formatted for screen readers, and inaccessible drop down menus are very difficult for people with various disabilities to navigate and use. That

remains the case, even if *some* of the information on the website is readily accessible. States and Medicaid MCOs that develop their websites to draw in and provide information to their enrollees should be prepared to ensure that the entire website is equally available to *all* enrollees.

Secondly, § 438.10(c)(6)(iii) should be amended to include the additional direction concerning forms and the enrollee's submission of information: “, ***and any applications or forms can be filled online, electronically retained, printed, and submitted online.***” Individuals who are blind and who use computers often do not use or own printers. The capacity to retain an electronic copy of their Medicaid application or their filled out plan complaint form, for example, while submitting the complaint electronically, will remove some substantial barriers that make it difficult for blind and visually impaired individuals to participate fully and as independently as possible in the management of their own healthcare.

§ 438.10(e)

We disagree with giving states the options to provide information to potential enrollees in either paper or electronic format. We recommend that states should be directed to provide both, and can give an individual potential enrollee only one format where the potential enrollee him or herself made an earlier election to receive only a single format.

We also recommend that there be an additional “catch-all” information category here, § ***438.10(e)(xi), that enables a potential enrollee to request additional information besides the enumerated elements, in a paper or electronic format.*** Many people with disabilities need very particular details about the amount, duration and scope of such benefits as DME, or mental health coverage or drug formularies, how and where to access such benefits, and any restrictions on enrollee choice of providers, before they can make a truly informed choice among Medicaid plans.

§ 438.10(g)(3)

This subsection indicates that MCOs are deemed to have provided enrollees with all required information if the MCO “mails a printed copy of the information to the enrollee's mailing address.” However, this makes little sense if the enrollee cannot read print and has already requested an alternate format from their MCO. In those cases, the MCO will be deemed to provide information to an enrollee when it is effectively providing the information in a format that it knows the enrollee cannot use. We suggest the following amendments to two of the subsections:

(i) Mails a copy of the information to the enrollee's mailing address ***in the alternate format requested by the enrollee; mailing a printed copy of the information to the enrollee's mailing address will be adequate provision of the information if the MCO has documented past efforts to effectively notify that enrollee of his or her right to readily accessible information.***

(iii) Posts the information on the Web site of the MCO . . . and advises the enrollee in the alternate format of his or her choice that the information is available on the Internet and includes the applicable internet address provided that enrollees with disabilities who cannot access this information online are provided ***readily accessible alternatives to online access.***

§ 438.10(h)(1)(vii)

CCD strongly supports the new information requirement for MCO provider directories to include information on the accessibility of network provider offices/facilities. People with various disabilities and functional limitations need accurate information about provider accessibility in order to receive effective healthcare services. Even though the ADA and Section 504 have placed accessibility and accommodation obligations on healthcare entities for well over two decades, physical and programmatic barriers remain pervasive.

For many years the disability community has only had anecdotal evidence of inaccessible healthcare service delivery, but increasingly studies and reports corroborate numerous ongoing issues. One of the first large-scale studies took place in California, specifically among providers who participate in managed care networks.

California regulations have long required MCOs to administer a "facility site review" (FSR) of their primary care provider networks. Basically the FSR procedure involves sending a plan representative, often but not necessarily a registered nurse, to provider sites to review a selection of files and such things as the temperature at which medications are stored. The FSR was performed on Primary Care Providers (PCPs) as they joined and every 3 years thereafter, perhaps taking a few hours per visit per site, depending on the size of the facility. Beginning around 2005, disability advocates began working with some of the state's MCOs to voluntarily include a physical access survey (PAS) as part of the MCO's administration of the FSR. The PAS focused on physical/structural accessibility but also included two equipment questions, one on height-adjustable exam tables and one on accessible scales. The plans agreed to participate because they were already reviewing their network offices, and it was impressed upon them that accessibility is important to the quality of care that members with disabilities receive; if the plan knew the accessibility of their providers, they could provide this information to members with disabilities and steer them to accessible providers as needed.

Ultimately, 4-5 CA plans administered a 55-question PAS with their FSR over an approximate 5 year period, from 2006-2010, obtaining results from over 2300 PCP office sites of varying sizes. The survey results were obtained by 3rd party reviewers trained in structural access requirements, everything from toilet seat heights to the weight permitted in exterior doors, and accessible equipment. The survey results were validated, analyzed and published in 2012, establishing that an accessible weight scale was present in 3.6% of the sites, and a height adjustable examination table in 8.4% of the sites.⁴ Other high prevalence access barriers were in bathrooms and examination rooms.

More recent research shows that accessibility is no better among specialists. A research team led by Dr. Tara Lagu attempted to find referrals for a fictional female patient with mobility disabilities and chronic conditions. Of the 256 specialty practices that were called, 56 (22%) reported that they could not accommodate the patient, 9 (4%) reported that the building was inaccessible, 47 (18%) reported inability to transfer a patient from a wheelchair to an examination table, and 22

⁴ Physical Accessibility in Primary Health Care Settings: Results from California On—Site Reviews Nancy R. Mudrick, Mary Lou Breslin, Mengke Liang, and Silvia Yee, *Disability and Health Journal* 5 (2012) 159-167.

(9%) reported use of height-adjustable tables or a lift for transfer. Gynecology was the subspecialty with the highest rate of inaccessible practices (44%).⁵ Researchers were sometimes simply and openly informed that the practice could not provide healthcare services “because the patient uses a wheelchair.”

We go into considerable detail on this issue because we fully support CMS’s comment at 80 FR 31162 that “meaningful access for [enrollees with disabilities] is available only when they can utilize the full scope of services at a provider’s office.” We believe that inclusion of this new element in provider directories is justified when for Medicaid MCOs must now serve people with long-held disabilities, functional limitations and chronic conditions, as well as older low-income individuals with newly acquired disabilities. These individuals and their families need basic information about provider accessibility to avoid wasted trips, pain, and embarrassment. They need accurate information from the beginning so they do not arrive at an appointment only to discover that the office was mistaken and the exam table does not really lower or bone density scans do not result in accurate images when a patient remains seated in a wheelchair. We are hopeful that the Access Board’s work on voluntary medical equipment accessibility standards will elevate provider awareness and compliance when the standards are eventually issued, and that the standards will eventually be adopted into regulation by the Department of Justice who will ideally add scoping requirements, but thousands of Medicaid beneficiaries need this information now.

While we wholly support the requirement for accessibility information in the provider directory, we do have some strong concerns with the current wording of the requirement.

First, we are disturbed by the limitation to accessibility for “people with physical disabilities.” CMS comments on this subsection discuss the need to ensure that “enrollees with limited vision and other impairments can reasonably access that information online as well as on paper, as well as in the delivery of services,” and accommodations for “deaf and hard of hearing enrollees who may need in-person ASL interpreters as well as the use of TTY/TDY lines and/or relay services.” In disability rights law we typically see ADA obligations, for example, broken down into structural/physical accessibility and reasonable accommodations and policy modifications. There can also be a broad division of disability “types” as physical or mental. The proposed rule seem to contemplate a full range of accommodations (i.e., ASL is an auxiliary aid or service that is provided as a reasonable accommodation or policy modification, rather than an issue of structural or physical accessibility), but *only* people with physical disabilities.

However, if a provider has to provide an electronic disc of post-surgery self-care instructions instead of a sheaf of papers to an enrollee who is blind, it would be entirely arbitrary to decide that the provider need not provide that same CD to someone with a learning or print disability who could equally benefit, but does not necessarily have a “physical” disability. Even more importantly, federal laws absolutely cover people with a full range of disabilities, and obligate

⁵ Access to Subspecialty Care for Patients With Mobility Impairment: A Survey, T. Lagu et al., *Ann Intern Med.* 19 March 2013;158(6):441-446. *See also* Accessible Medical Equipment for Patients with Disabilities in Primary Care Clinics: Why Is It Lacking?, J. Pharr, *Disability & Health J.* April 2013, 6(2): 124-132; Predicting Barriers to Primary Care for Patients with Disabilities: A Mixed Methods Study of Practice Administrators, J. Pharr and M. Chino, *Disability & Health J.* April 2013, 6(2):116–123.

covered entities to provide accommodations to anyone with a disability, including those who have a "physical or mental impairment that substantially limits" such major life activities as learning, reading, concentrating, thinking, communicating, and so forth. The current wording of § 438.10(h)(1)(vii) erroneously assumes that ADA/504 rights are somehow privileged in their application to people with physical disabilities, and providers need not provide information or bother with the accommodations that are relevant to people with mental or intellectual disabilities.

If a patient with autism or an intellectual disability requires more time for an examination, that accommodation request is as much a legal obligation as a request for additional time that comes from someone who has a physical disability that affects their speech, but as currently written, the rule implies that only the latter example counts when it comes to getting the "full scope of services at a provider's office." Information about the kinds of programmatic accommodations that people with mental disabilities might need, such as extended appointment times or appointment windows, or policies that will allow someone with a mental health disability to be accompanied by their service animal in healthcare facilities, cannot be independently collected in the same way as a door width can be measured, but that does not mean it would not be possible for a trained 3rd party MCO representative to collect this information through brief interviews as part of a network site review. Inclusion of the full breadth of accommodations needed by people with physical and mental disabilities will help educate providers about their broader ADA/504 obligations, as well as help states to collect baseline accommodation information that can be placed in directories.

We recommend amending § 438.10(h)(1)(viii) as follows:

(viii) Whether the provider's office/facility ***provides physical access, accessible equipment, reasonable accommodations and policy modifications, and effective communication for people with physical or mental disabilities.***

This wording generally matches the phrasing used in § 438.68(c)(viii) to describe an element that must be considered by the state when developing time-distance network adequacy standards. However we recommend not replacing "Medicaid enrollees with physical or mental disabilities" with "people with physical or mental disabilities" because the former phrase seems to exclude family members or guardians of minor Medicaid enrollees (or adults with significant intellectual disabilities for example) who may have disabilities that require accommodation, in contradiction of federal disability rights law. We also recommend this change in phrasing for § 438.68(c)(viii), as well as for § 438.206(c)(3). All three provisions should be consistent in their reference to physical accessibility, accessible equipment, reasonable accommodations and policy modifications, and effective communication for people with physical or mental disabilities.

As our final key point, we strongly urge that the proposed rule establish parameters for both how MCOs collect accessibility information on their provider network, and for how states will monitor and ensure the accuracy of accessibility information. People with disabilities will not receive the full scope of services at MCO providers' offices unless they have access to reliable, consistently measured and updated information on the accessibility of all kinds of MCO provider offices, including PCPs, specialists, hospitals, pharmacists, LTSS providers, and treatment centers such as dialysis or mobile diagnostic centers. Research has established the human tendency to overlook

the need for accessibility or accommodations that one does not need oneself. One study found significant discrepancies between provider self-reporting about office accessibility via a telephone survey, and a subsequent site accessibility analysis made by a team of surveyors that conducted an on-site assessment of parking, building entrance, examination room, and restroom accessibility at the same site.⁶

California's experience with MCO administration of the FSR and PAS proves that it *is* possible to obtain reliable and consistently measured accessibility information about a provider network. An expanded physical access survey is now a mandatory component of the California FSR.⁷ All Medicaid managed care plans, including the dual integration plans, must administer the PAS to both their network PCPs, specialists and ancillary providers, as mandated under both the special terms and conditions approved under the state's last 1115 waiver renewal and the three-way contracts in the duals project. Moreover, the fact that all MCOs must administer a consistent survey tool has enabled plans to enter agreements with one another that will allow one plan's survey of a provider office/facility that contracts with multiple plans to fulfill the FSR obligation of all the plans with respect to that specific office. This fosters efficiency and avoids a provider having to undergo multiple FSR evaluations in a given period. Additional targeted training of the MCO FSR administrators would enable them to administer a component directed at obtaining information about reasonable accommodations and policy modifications in provider offices.

While MCOs in California are administering the FSR and PAS, the gathering of survey information has not necessarily led to the publication of accurate and current provision of PAS results in provider directories. MCOs are not given a uniform or model way of reporting accessibility information, and there appear to be few resources devoted to state monitoring of PAS results. Similarly, the PAS administration has not necessarily led to improved accessibility among provider networks. Some FSR issues may lead to a corrective action plan for MCOs, but provider network inaccessibility does not trigger corrective actions or result in any requirement to improve network accessibility.

Section 438.206(c)(3) in the proposed rule, is meant to support the requirement, in § 438.68(c)(1)(vii) that a state's network adequacy standards consider "the ability of healthcare professionals to ensure physical access, reasonable accommodations, culturally competent communications, and accessible equipment for Medicaid enrollees with physical or mental disabilities." As such, § 438.206(c)(3) echoes the prior network adequacy section and requires MCOs to "ensure" that network providers "provide physical access, accommodations, and accessible equipment for Medicaid enrollees with physical or mental disabilities. Section

⁶ Perceived accessibility versus actual physical accessibility of healthcare facilities. Sanchez J, Byfield B, Brown TT, LaFavor K, Murphy D, Laud P. Rehabil Nursing. 2000;25:6-9.

⁷ The policy behind the administration and development of the PAS is captured in a 2012 California Department of Health Care Services All Plan Letter, available at:

<http://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/PL2012/PL12-006.pdf>. The PAS itself is attached to this letter. A 2014 DHCS All Plan Letter provides the history of the FSR and also includes the FSR as an attachment, available at:

<http://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/PL2014/PL14-004.pdf>.

438.206(c) in turn holds the state responsible for ensuring that each MCO contract contains the MCO's obligation to ensure accessibility in its provider network.

We recommend that § 438.206(c)(3) explicitly incorporate the provider directory requirements of § 438.10(h)(1)(viii) as follows:

(3) Accessibility considerations. Each MCO, PHP, and PAHP must ensure that network providers provide physical access, accessible equipment, reasonable accommodations and policy modifications, and effective communication for people with physical or mental disabilities. MCOs shall ascertain, on an ongoing basis, the extent to which network providers are currently capable of meeting their accessibility obligations and shall make this information available through provider directories, in accordance with § 438.10(h)(1)(viii).

The suggested amendment would strengthen the relationship between the information requirements and network adequacy, and give states a concrete way to monitor MCO efforts to increase needed accessibility among their provider networks. We also recommend that the rule explicitly recognize MCO efforts to improve accessibility and reduce accessibility barriers within their provider networks, including efforts to implement health information technology that would allow enrollee accommodation needs to be captured in electronic health records and allow provider office accessibility to be updated by enrollees, to be counted towards the MLR numerator as activities that improve healthcare quality.

A review of 45 C.F.R. §158.150 and §158.151 shows the degree to which activities that clearly improve clinical care and healthcare quality for people with various disabilities, such as the removal of physical accessibility and the provision of reasonable accommodations and policy modifications, do not fit neatly within established clinical and evidence-based parameters that historically have been developed for and applied within a disability-free population. The same analysis holds true for disability-specific best practices that implicate LTSS, such as the implementation of *Olmstead* training and the broad implementation of home and community-based services that is required under that Supreme Court decision, and yet this is a core MLTSS principle recognized by CMS in the proposed rule. We strongly urge CMS to consider and enunciate how the MLR could be used to help incentivize and encourage MCO activities that will remove accessibility barriers among providers and encourage community integration among enrollees with disabilities, including MCO collection of accurate information on accessibility within provider networks

Subpart B State Responsibilities

438.54 Managed care enrollment

CCD thanks CMS for including protections for beneficiaries in the enrollment process. However, we think that many of these protections do not go far enough and strongly encourage CMS to strengthen them.

The 14-day choice period in §438.54(c)(2) and §438.54(d)(2) is not nearly sufficient to allow beneficiaries, particularly beneficiaries with disabilities, to make an informed choice. Many of the demonstrations to integrate administration and/or financing for dually eligible beneficiaries currently being conducted by CMS allow for 60-day choice period, with multiple notices within that period. Fourteen calendar days is simply not enough time to complete the tasks necessary for a beneficiary with a disability to choose a plan, which can include locating new provider networks, researching providers, comparing benefit plans, contacting the Beneficiary Support System, receiving choice counseling, weighing options, and making an informed and thoughtful decision. These beneficiaries are less likely to fully understand the notices when they arrive, more likely to have a language barrier, less likely to have a computer or internet at home on which to conduct research, and more likely to need accommodations and support throughout the process, including support from family members who may not live in the area. In order to receive proper support through the process, beneficiaries may need to arrange child care, request time off of work, and arrange transportation. If an office is unable to meet their accommodations at that time, they may need to repeat the process over again. Depending on the arrival date of the notice, the 14 calendar day period could be effectively 10 days, if the 14 day period covers two weekends when physicians or BSS offices may not be open. We suggest, at a minimum **a 30-calendar day choice period and would strongly prefer 60 days.**

For those disabilities who require an alternative format, there is little indication that enrollment information must be provided in alternative formats that will enable a beneficiary with vision or print disabilities to receive the alternate format that will allow them to read and weigh enrollment information and notices independently in **at least the same time frame** as that allotted to other enrollees. Section 438.10 currently gives MCOs 438.10(c)(6)(v) up to five calendar days to meet a request from “an enrollee” to get information that a state/MCO typically only provides in [accessible] electronic form in a paper form. This is the section’s only specific timeline, and not only does it appear to not apply to the information that a NON-enrollee needs to get when making an enrollment decision, the 5 days that it references eats up more than 1/3 of the 14 calendar day choice period provided in the enrollment section, placing individuals who need alternative formats and who are therefore **already** facing barriers to obtaining and reading the additional information they need to make an informed choice (e.g., comparing provider networks, drug formularies, getting info from independent choice counselors, etc.) under a considerable disadvantage that the proposed rules fail to address.

We appreciate that CMS recognizes the importance of not only providing enrollees with sufficient time, but also adequate information to make an appropriate plan selection. We strongly support the 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 also the implications of making a plan 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 CMS to require states to include in the informational packets enrollment and disenrollment forms.

To preserve the truly voluntary nature of voluntary managed care programs, §438.54(c)(2)(i) must be changed to state that if the enrollee does not make an active choice during the choice period, the potential enrollee will remain enrolled in fee-for-service Medicaid. Enrolling a beneficiary after such a short choice period, and only one written notice, in a default enrollment system is effectively passive enrollment, not active enrollment. Active voluntary enrollment should be opt-in. At a minimum, the regulation should allow for truly active opt-in enrollment. As currently written, the regulations only allow for Voluntary Active Opt-out, Voluntary Passive Opt-Out, and Mandatory enrollment. We suggest the following changes:

- (i) If the State ~~does not use a passive~~**uses an active opt-in** enrollment process and the potential enrollee does not make an active choice during the choice period, the potential enrollee will **remain enrolled in fee-for-service or their existing MCO, PIHP, PAHP, PCCM, or PCCM entity, if available.** ~~be enrolled in a MCO, PIHP, PAHP, PCCM, or PCCM entity by the state using its default process. The enrollment into the MCO, PIHP, PAHP, PCCM, or PCCM entity will become effective after the end of the choice period.~~
- (ii) If the State **uses an active opt-out** ~~does not use a passive~~ enrollment process and the potential enrollee does not make an active choice during the choice period, the potential enrollee will be enrolled in a MCO, PIHP, PAHP, PCCM, or PCCM entity by the state using its default process. The enrollment into the MCO, PIHP, PAHP, PCCM, or PCCM entity will become effective after the end of the choice period.
- (iii) If the State used a passive enrollment process...

We support §438.54(c)(6) that a passive enrollment process must seek to preserve existing provider-beneficiary relationships and providers that have traditionally served Medicaid beneficiaries. We also recommend that, if possible, the state establish a passive enrollment process that incorporates providers with experience serving Medicaid sub-populations. Providers with experience serving children, older adults, low-income families, and people with disabilities may offer very different service and expertise.

- (6) A passive enrollment process must seek to preserve existing provider-beneficiary relationships and relationships with providers that have traditionally served Medicaid beneficiaries. ***This includes matching beneficiaries to plans with providers that have traditionally served the Medicaid sub-population to which they belong, such as people with developmental disabilities, people with physical disabilities, older adults, and families with children.***

We strongly support the inclusion of accessibility of provider offices for people with disabilities as additional criteria under which to conduct the passive enrollment process in §438.54(c)(7)(ii). We suggest that CMS strengthen this requirement by requiring the state consider these criteria.

- (iv) The State **must** ~~may~~ consider additional criteria...

We also noticed that accessibility of provider offices is not included in the additional criteria to conduct the default enrollment process under mandatory managed care programs in §438.54(d)(7)(ii). All other criteria from §438.54(c)(7)(ii) are carried into §438.54(d)(7)(ii), except

for physical and programmatic accessibility of provider offices. We expect that this is an oversight and hope to see it included in the final rule.

§ 438.56 Disenrollment Requirements and limitations

CCD thanks CMS for including disenrollment rules and protections, particularly in the area of LTSS.

We strongly support §438.56(b)(2) that a plan may not request disenrollment because of an adverse change in the enrollee's health status, or because of the enrollee's utilization of medical services, diminished mental capacity, or uncooperative or disruptive behavior resulting from his or her special needs. We seek clarification on the provision "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." We recognize that this is part of existing regulations and is not a change in this proposed rule, but believe that this provision allows for discrimination based on disability, and undermines the protection listed earlier in the section against disenrollment for "uncooperative or disruptive behavior resulting from [the beneficiary's] special needs."

We support §438.56(d)(2) causes for disenrollment, especially part (iv) requesting disenrollment for cause includes situations where the enrollee would need to change MLTSS providers based on a change of the provider's in-network status. However, the situations that currently qualify for "cause" for disenrollment are too limited, especially since the NPRM proposes to limit disenrollment without cause to only once per enrollment period (which, for reasons we describe later, 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 CMS 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 and when there has been a breakdown in the physician-patient relationship. Finally, CMS 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.

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 or other conditions affecting behavior. We urge CMS 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. CMS should strengthen this rule to add a prohibited ground for discrimination. Specifically, CMS 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 since in some states, like California, some Medicaid enrollees have no choice in plan (and therefore no alternative plan in which to enroll if the plan improperly disenrolls the enrollee) because there is only one Medicaid plan offered in the area.

Recommendation: §438.56 (b)

- (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.***

CMS' 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 if they realize soon after enrolling that the plan cannot, or will not, meet their needs, especially if the enrollee has other possible options. We strongly oppose CMS' proposal to limit enrollees to only one 90-day without cause disenrollment per enrollment period. We suggest that CMS 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: §438.56(d)

- (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, 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.

§ 438.62 - Continued services to enrollees

We commend CMS 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 CMS'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 § 438.52.

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.

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

In addition, we are 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 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. Likewise, a child with a serious, complex and/or fragile medical condition may have developed a relationship and painstakingly-achieved a course of treatment with a particular pediatric subspecialist, or may have a history of treatment at a particular children's hospital which has specialized expertise in that child's condition. While it may be difficult to prove that the patient would suffer "serious detriment to their health or be at risk of hospitalization or institutionalization," the child would certainly be at risk of a serious detriment to their health, psychological well-being, development, and/or level of functioning if access to that provider is lost.

Accordingly, we urge CMS to amend the criteria for when a state must require plans to offer continued access to out-of-network providers, as described below.

We recommend amending § 438.62(b) as follows:

§ 438.62(b) 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 prenatal or post-partum care, has a long-term relationship with a provider for treatment of a serious, complex, chronic medical condition, or the state determines that other circumstances warrant continued access.***

§ 438.68 Network adequacy standards

We strongly support the addition of this new section on network adequacy to the proposed regulations. For too long, the Medicaid managed care program has lacked specific network adequacy standards aimed at ensuring that consumers can actually get care from their Medicaid plans.⁸ These proposed provisions add significant detail to guide states and Medicaid plans in

⁸ See, e.g., SUZANNE MURRIN, DEPT. OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GENERAL, STATE STANDARDS FOR ACCESS TO CARE IN MEDICAID MANAGED CARE 19 (2014) ("CMS and States need to do more to

developing their networks to ensure adequacy. We appreciate CMS's attention to the network needs of LTSS. We are not aware of any other home and community-based LTSS-specific network adequacy standards at the federal or state level. We encourage CMS 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 CMS for requiring plans to publish their network adequacy standards in § 438.68(e). 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 CMS 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 for the website for their state Medicaid program.

We strongly support the 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 with the 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, CMS 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. We are concerned, however, that CMS has erred too far on the side of broad standards and state discretion. By permitting each state to set its own time and distance standards without any outside limits set by CMS, we are concerned that standards will vary too widely from one state to another, and that oversight by CMS will continue to be fragmented.⁹ As described in more detail below and in our comments to §§ 438.206-.207, we suggest that CMS adopt specific minimum standards in the areas of geographic access, provider-patient ratios, and timely access to care.

We appreciate that CMS 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.¹⁰ Thus, we do not believe that CMS'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 CMS to work with states that have higher standards in place to maintain those standards in light of new federal minimums.

ensure that all States have adequate access standards and strategies for assessing compliance.”), *available at* <http://oig.CMS.gov/oei/reports/oei-02-11-00320.pdf>; *see also, e.g.,* ABBI COURSOLE, 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-issue-3>.

⁹ *See* MURRIN, *supra* note at 8-9 (describing various state standards for travel time and distance, ranging from 5 miles in two states, to 100 miles in two other states).

¹⁰ *Id.* at 8-12.

§ 438.68(b)(1) – *Provider Specific Standards*

We are pleased that CMS 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 CMS for delineating in this section the provider types for which states must develop geographic access standards. We applaud CMS for capturing key provider types that must form the foundation of a network for any comprehensive Medicaid managed care plan.

§ 438.68(b)(2)

For the same reasons that we believe they are necessary in other types of services, we strongly recommend that CMS 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 CMS 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 CMS convene a group of experts and interested parties to formulate these recommendations. Within 6 months of finalizing these regulations, CMS 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 CMS, including CMS, SAMHSA, OCR; the Administration for Community Living; state Medicaid agencies; managed care plans; Medicaid beneficiaries – including people with disabilities – and Medicaid beneficiary family members and advocates; and researchers. CMS 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 CMS sets out network adequacy standards for Medicare Advantage plans on an annual basis.

Recommendation:

Amend § 438.68(b)(2) as follows:

- (2) *LTSS*. States with MCO, PIHP or PAHP contracts which cover LTSS must develop:
 - (i) 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
 - (ii) 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.

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

CCD thanks CMS for requiring stakeholder engagement at both the state and MCO, PIHP, or PIHP level. As CMS recognized in their 2013 guidance, “Stakeholders (including participants) are essential partners in the program design and planning phases as well as the implementation and oversight phases of an MLTSS program.”

We recommend that the stakeholder group outlined in §438.70 include, at a minimum, people with disabilities, family caregivers, LTSS providers, disability and aging advocacy organizations, and the entities of the Beneficiary Support System (outlined in §438.71) that provide the functions specific to LTSS activities (outlined in §438.77(e)). The stakeholder group should be empowered with access to quality reports, LTSS program data collected by the Beneficiary Support System, information from state *Olmstead* committees, and reports from Long-Term Care, Duals Demonstration, or other MLTSS Ombudsman.

We also recommend that CMS incorporate the language from the 2013 MLTSS guidance on stakeholder engagement, including

- Ensuring that “consumers must be offered supports to facilitate their participation, such as transportation assistance, interpreters, personal care assistants and other reasonable accommodations, including compensations, as appropriate.”
- Ensuring that frequency of meetings is based on recommendations from the stakeholder group to ensure meaningful stakeholder engagement.
- Providing opportunities for broader public input, “including holding events in accessible locations around their states and providing other means of input for those who are unable to obtain meetings in person, such as the use of remote site technology or web-based input opportunities.”

Robust standards, and CMS 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®.

CMS 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.

§431.504(a) requires the state comprehensive quality strategy to obtain input from the Medical Care Advisory committee in the development of the strategy. We recommend that the stakeholder

group outlined in §438.70 also provide input into the development of the state comprehensive quality strategy.

We also recommend that CMS set a floor for frequency of stakeholder group meetings, at least quarterly, and more frequently when states are designing and planning transitions to managed care or other significant system changes. The “sufficiency” standard proposed by CMS is too broad and too vague to allow for meaningful and sustained stakeholder engagement.

However, stakeholder engagement should not be limited to the stakeholder group. In addition to the group, states and MCOs, PIHPs, and PAHPs must reach out to the broader community of people with disabilities older people, and their families who use LTSS.

438.71 Beneficiary Support System

CCD strongly supports creation of the Beneficiary Support System to support and protect beneficiaries prior to and after enrollment in managed care, especially in the area of LTSS. Beneficiaries with disabilities are often high utilizers of services and may need supports to understand their rights and obligations in the managed care system.

We recommend that this system build on existing community-based navigation, information and referral, advocacy, and ombudsman groups, such as Centers for Independent Living, Aging & Disability Resource Centers, Family-to-Family Health Information Centers, Protection & Advocacy agencies, Legal Aid, Developmental Disabilities Councils, University Centers for Excellence in Developmental Disabilities, State Health Insurance Programs, Area Agencies on Aging, and others. Most of these programs are administered by the Administration for Community Living and operate at the state level; states should take advantage of existing infrastructure, expertise, and federal investment in community-based support for people with disabilities. In this vein, we strongly support the provision at §438.71(e)(3)(i) that 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. Many of these entities already provide choice counseling and representation, and have already established appropriate firewalls to endure independence and avoid conflicts of interest.

In §438.71(e)(4) we recommend that the Beneficiary Support System go beyond “review and oversight of data” and fulfill an Ombudsman purpose. This may be accomplished through contracting with and expanding the duties of existing Long-Term Care Ombudsman to include managed care and home and community-based services. This should include overseeing the network adequacy for LTSS by collecting beneficiary complaints and review of service plan authorizations compared to actual claims experience.

We recommend that outreach activities described in §438.71(b)(2) be “readily accessible” as defined in §438.10(a).

We strongly support the functions specific to LTSS activities, but believe these should be expanded to all Medicaid beneficiaries in managed care. All Medicaid beneficiaries will benefit

from having access to a single point for complaints, education on grievance and appeal, assistance navigating the grievance and appeal process, representation at hearings and review and oversight of program data. Incorporating all populations and all services into the Beneficiary Support System would also further program goals of an integrated system. Beneficiaries who use LTSS should not be required to seek assistance from one entity navigating the system for their LTSS and another navigating the system for their acute, primary, or behavioral health care needs. For example, the BSS should collect program data on access to LTSS, as well as complaints about accessibility of information as required in §438.10, physical accessibility of physician’s offices, and other access barriers.

We are very concerned that the estimated System costs (ICRs Regarding Beneficiary Support System, pg. 31182) undervalue its importance and the resources needed to develop and maintain a quality System. The ICR estimates establishing the choice counseling system will require 125 hours of work, and the beneficiary assistance will be completed by a call center and existing ombudsman staff. As proposed, these estimates will ensure the System fails to meet beneficiary needs. At best, the System will be able to offer a limited use call center. A thriving beneficiary support network requires time and resources that exceed the current estimations.

CMS has clarified how states can receive an administrative matching rate for services provided through the beneficiary support system. However, there needs to be greater opportunities for stakeholder engagement and monitoring to ensure that states establish and provide adequate resources meet the needs of beneficiaries.

Recommendations

We recommend adding to the list at § 438.66(b) as a new number (13) (the remainder renumbered) ***“Adequacy of Beneficiary Support System”***.

In addition, we previously recommended that the MLTSS advisory committee in § 438.70 must be consulted in the review of state monitoring activities.

Subpart C Enrollee Rights and Protections

§438.100 Enrollee rights

We support these provisions, but urge CMS to make the following change:

(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 (including: Title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 CFR part 80; 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, ***including as interpreted by Olmstead v. L.C. 527 U.S. 581 (1999)***).

438.110 Member Advisory Committee

CCD supports the requirement that each MCO, PIHP or PAHP establish and maintain a member advisory committee. However, the proposed rule is too broad and too vague to allow for meaningful and sustained stakeholder engagement. In addition to the requirement that the committee include at least a reasonably representative sample of the LTSS populations covered, plans should also:

- Ensure that “consumers must be offered supports to facilitate their participation, such as transportation assistance, interpreters, personal care assistants and other reasonable accommodations, including compensations, as appropriate.”
- Ensure that frequency of meetings is based on recommendations from the stakeholder group to ensure meaningful stakeholder engagement.

Subpart D MCO, PIHP, & PAHP Standards

§438.206 Availability of Services

§ 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 the decision to explicitly call out the plan’s responsibility for ensuring access, accommodations, and appropriate equipment for enrollees with both physical and mental disabilities and want to be clear that it requires a broad range of accessibility. Similar to our comments earlier, we recommend that CMS 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. CCD also notes that the ADA and/or Section 504 would cover individuals beyond enrollees or potential enrollees with physical or mental disabilities.

We recommend amending § 438.206(c)(3) as follows:

§ 438.206(c)(3) *Accessibility considerations*. Each MCO, PIHP, and PAHP must ensure that network providers provide physical access, **reasonable accommodations and policy modifications**, ~~and~~ accessible equipment, **and effective communication** 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 and others who would be covered by the ADA and/or Section 504 such as parents, spouses, family members of minor children or adults with disabilities.**

§ 438.210 – Coverage and authorization of services

For authorization of services, the contract between a state and the plans must “authorize LTSS based on an enrollee’s current needs assessment and consistent with the person-centered service plan.”¹¹ CCD believes that CMS should stress that this LTSS includes HCBS.

We commend CMS 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.

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

We appreciate that in the first three subdivisions of § 438.210(a), CMS will continue to explicitly require states to identify the amount, duration and scope of coverage in their contracts with plans. We also applaud CMS 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.

§ 438.210(a)(4)

We appreciate that CMS has placed the requirements for plans’ limitations on services in a separate subdivision. 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 CMS 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 CMS 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 CMS 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 in order to continue receiving services;

¹¹ See *Medicaid Managed Care*, § 438.210(b)(2)(iii), at 31277.

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 enrollee 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 wellbeing of those with chronic conditions over the long term. CMS 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% 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 CMS to work with states to stop plans from using utilization criteria that prioritize cost over effectiveness and over-all 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 CMS in conjunction with other federal departments.¹² 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. CMS should make clear that these factors are to be considered in the utilization review process.

We recommend amending a § 438.210(a)(4) as follows:

- § 438.210(a)(4) Permit an MCO, PIHP, or PAHP to place appropriate limits on a service—
- (i) On the basis of criteria applied under the State plan, such as medical necessity; or
 - (ii) For the purpose of utilization control, provided that
 - (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***

¹² 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.

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.

(VIII) The disclosure required by paragraph (VI) of subdivision (a)(4)(ii) shall be 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."

(B) The services supporting individuals with ongoing or chronic conditions or who require long-term services and supports are authorized in a manner that meets the enrollee's ongoing need for such services and supports; and...

§ 438.210(a)(5) – *Medical necessity definition*

We commend CMS for expanding this section to give more guidance to states and plans in defining medical necessity. We strongly support CMS'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 CMS 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, a CCD member 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. In order to avoid this kind of legal violation, they suggest that CMS 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 CMS added to this section to account for EPSDT. We suggest that CMS 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 CMS 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).

The list item at (a)(5)(iii)(D) seems to suggest that, in defining “medically necessary,” managed care entities could limit the extent to which the requirements of Title II of the ADA and the Olmstead decision apply.

We recommend amending a § 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) Meets the requirements of Title II of the ADA and Olmstead v. L.C. to ensure that individuals with disabilities are served in the most integrated setting appropriate to their needs; and***
- ~~(iii)~~ ***(iv) Addresses the extent to which Requires the MCO, PIHP, or PAHP is responsible for to provide services covered in the contracting services that address:***
- (A) The prevention, diagnosis, and treatment of an enrollee's disease, condition, and/or disorder that results in health impairments and/or disability.
 - (B) The ability for an enrollee to achieve age-appropriate growth and development.

- (C) The ability for an enrollee to attain, maintain, or regain functional capacity.
- (D) The opportunity for an enrollee to receive long-term services and supports that offer the greatest opportunities for active community participation and high quality of life.¹³

§ 438.210(b) – *Authorization of services*

We commend CMS for significantly expanding this section to account for the needs of enrollees using LTSS and behavioral health. We commend CMS 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 plan 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 CMS 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 CMS 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).

Finally, we suggest that CMS add language to this section to delineate 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 CMS make these requirements explicit in the regulation.

We recommend amending a § 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***

¹³ See Element 3 of Guidance to States Using 1115 Demonstration or 1915(b) Waivers for Managed Long-Term Services and Supports. <http://www.medicaid.gov/medicaid-chip-program-information/by-topics/delivery-systems/downloads/1115-and-1915b-mltss-guidance.pdf>

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) *Shall not require prior authorization for family planning services and supplies consistent with paragraph (a)(4)(ii)(C) of this section.*
- (v) *Shall provide covered non-emergency transportation services whenever an enrollee needs transportation in order 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 in order 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 before 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, retroactive authorization will be entered when the MCO, PIHP, or PAHP makes a decision on the request.*
- (iii) If the prescribing provider submitted the request at least 10 calendar days prior to the end of the current authorization period and the request is denied 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.*

(34) That any decision to deny 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. (For example, a pediatrician or pediatric subspecialist should review requests for services provided to a child.)

§ 438.214 Provider Selection

§ 438.214(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. We therefore suggest that subsection (c) be divided into two subsections to include this generally nondiscrimination provision.

Revise § 438.214(c) to include a general nondiscrimination provision:

(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.~~

(1) discriminate against particular providers on the basis of their race, color, or national origin, language, disability, age, sex, gender identity, or sexual orientation.

(2) Selection criteria shall not be established in a manner:

(a) That would allow a health carrier to discriminate against high-risk populations by excluding providers because they are located in geographic areas that contain populations or providers presenting a risk of higher than average claims, losses or health care services utilization; or

(b) That would exclude providers because they treat or specialize in treating populations presenting a risk of higher than average claims, losses or health care services utilization

§ 431 Subpart 1 General Provision and § 438 Subpart E Quality Measures and Improvements; Eternal Quality Review

§ 431.502 - State comprehensive quality strategy

CCD supports the establishment of an overall state comprehensive quality strategy that applies across fee-for-services and managed care. However, we are concerned that proposed language in the regulation is not strong enough to ensure broad-based, meaningful consumer stakeholder engagement from the LTSS community.

In addition to obtaining input from the Medical Care Advisory Committee, states should be required to also obtain meaningful stakeholder input from a subcommittee or other mechanism to ensure adequate attention to LTSS (as indicated in the 2013 CMS guidance on MLTSS). This subcommittee should be linked to stakeholder engagement in §438.70

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.¹⁴ 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 resolve the longstanding inequities in our health care system. Age is another important demographic to include when collecting the data.

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.¹⁵ HHS has also produced reports with recommendations on how to improve data collection for health disparities in Medicaid and CHIP.¹⁶ Health disparities are, however, mentioned just once in these proposed regulations and only in the context of network adequacy, not quality measurement.¹⁷ 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.

Recommendation:

Amend § 431.502(b)(1) to include a broad understanding of health that includes an individual's quality of life and well-being:

¹⁴ 42 U.S.C. § 300kk, (codifying ACA § 4302(a)).

¹⁵ *Adult Medicaid Quality Grants Program*, CMS, <http://medicaid.gov/medicaid-chip-program-information/by-topics/quality-of-care/adult-medicicaid-quality-grants.html> (last visited July 8, 2015).

¹⁶ Kathleen Sebellius, HHS, *Report to Congress: Approaches for Identifying, Collecting, and Evaluating Data on Health Care Disparities in Medicaid and CHIP* (Sept. 2011), <http://www.medicicaid.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* (Nov. 2014), <http://www.medicicaid.gov/medicaid-chip-program-information/by-topics/quality-of-care/quality-of-care-health-disparities.html>.

¹⁷ See 80 Fed. Reg. 31146.

(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 that include not a single change to the original proposal. To avoid such problems and ensure meaningful stakeholder engagement in the proposed CQS drafting process, we urge HHS to add significant detail to flesh out its vision for a robust CQS public comment process.

We believe the best recent model for transparent public engagement would be the regulations governing the comment process for § 1115 demonstration projects. This approach includes a 30-day comment period at the state level, a requirement for at least two public hearings and the posting of a detailed draft plan on the state website, and a requirement that the state include a response to public comments collected (along with a description of whether it incorporated these changes) in the draft it submits to CMS.¹⁸ 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;

¹⁸ 42 C.F.R. § 431.408.

- 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.

§ 438.310 - Basis, scope and applicability

CCD generally supports CMS’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 protections moving between providers are important components of access to care, particularly for individuals who require LTSS. The care coordination provision at § 438.208 includes standards for direct access to specialists and requires the MCO to have adequate and appropriate staffing to properly manage care, identify individuals with chronic conditions or LTSS needs, and conduct needs assessments and treatment and service plans for such individuals. These facets of care planning are central to the concept of “access” and should be considered as part of the validation of MCO, PIHP and PAHP networks.

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 a variety of protocol 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.¹⁹ We suggest that CMS 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 CMS include a broad definition of the term “outcome” that recognizes the importance of 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.

¹⁹ 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>.

Finally, the use of the term “review” in the definition of “validation” could be construed to preclude the creation of new data as part of the validation process, such as through a secret shopper or beneficiary survey used to validate a plan’s network adequacy. We suggest adding a reference to “direct testing of” after “review” to ensure that validation encompasses the types of direct testing CMS proposes will comprise the network adequacy validation protocol laid out in § 438.358(b)(4). We also suggest that CMS define the term “direct testing” in the regulations for better clarity.

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)**.

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.

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.

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

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

While we understand that a particular measure may not be relevant for a certain population, we strongly recommend that CMS strictly limit its proposed exceptions process by enumerating a set of specific reasons a state may obtain an exception and setting time limits on how long an exemption could last without review and extension. We agree with CMS that legitimate exceptions could include not collecting a measure that is irrelevant to the managed care covered population in a state and not including a required metric that measures the quality of a service not covered by or relevant to the managed care contract.²⁰

We strongly disagree with the preamble suggestion that a state might qualify for an exemption if it surpasses a defined threshold for multiple years.²¹ For many measures, such as certain vaccinations or the frequency of "never events," a threshold of 90% would not be considered successful. Even if CMS 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 then exempt its managed care entities from reporting that metric could thus undermine CMS's broader efforts to identify and reduce health disparities across key demographic groups. If CMS were to go forward, against our recommendation, 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.

²⁰ 80 Fed. Reg. 31150.

²¹ *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 applaud CMS for requiring PCCM entities to establish and maintain mechanisms to detect over- and underutilization of services under § 438.330(b)(3), like other managed care entities. Such mechanisms can be important tools to detect potential misuse, identify access barriers, and evaluate network adequacy.

CCD applauds the inclusion of LTSS in the basic elements of quality assessment and performance improvement program in section §438.330(b)(5). In the preamble, CMS encourages states to consider the use of surveys to assess the experience of beneficiaries receiving LTSS as a key component quality assessment. Due to the individualized and person-centered nature of LTSS, assessing beneficiary experience is essential. Many states currently use beneficiary surveys (such as the National Core Indicators, Council for Quality and Leadership Personal Outcome Measures , and other consumer and family surveys) to assess a variety of quality domains and to set benchmarks for improvement at the provider, plan, and state levels. In addition, a Home and Community-Based Experience survey is currently under development with anticipation of CHAPS certification and NQF endorsement in the near future. While there is a need for state flexibility, CCD urges inclusion of the following language requiring “assessment of LTSS beneficiary experience” as a basic element.

In addition, the term “treatment plan” is often used in a medical context and does not fully capture the scope and person-centered nature of LTSS. We proposed a minor modification for better alignment.

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. We urge CMS to also require states to include measures related to care coordination, the needs assessment process, and self-direction, in states that implement this option.

In the preamble CMS also acknowledges the importance of self-direction, encouraging states whose MLTSS programs include a self-directed option to include measures specific to self-direction. CCD urges the inclusion of stronger language in the regulations that would require such measures. As CMS alluded to in its 2013 MLTSS guidance to states, there are potential concerns and opportunities related to self-direction as states move to managed care. We believe it is essential to have quality measures to assess opportunities, supports, and outcomes related to self-direction.

While we support non-duplication and alignment, we are concerned about the provision at §438.330(d)(3) allowing MCOs, PIHPs, and PAHPs serving only dual eligibles to substitute MA Organizational quality improvement projects will reduce the likelihood of LTSS related performance improvement projects. We recommend that plans substituting with MA quality improvement projects also ensure that LTSS related performance improvement projects are included based input from the member advisory committee (448.10).

Recommendation:

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 CMS, against our recommendation, permits exemptions based on sustained achievement, the thresholds must be appropriate for each measure and states should have to prove that no significant disparities exist for key demographic groups prior to receiving a time-limited exemption.

Amend paragraph (c) as follows:

- (iii) *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 service***, and community integration activities for beneficiaries receiving LTSS.
- (iv) (Have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees using LTSS, including assessment of care between care settings, ***assessment of LTSS beneficiary experience***, and a comparison of services received with those set forth in the enrollee's treatment plan ***and an assessment of services and supports received to achieve goals and outcomes set forth in the enrollee's person-centered plan.***

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

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

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.”²² To the extent they are available for purchase, they may be quite expensive. Private entities’ standards and measures must be readily and publicly available at no or nominal cost, or should be determined by the state after a robust stakeholder engagement process. 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, CMS has included no indication that this accreditation process will be specific to the Medicaid business line of a participating MCO, PIHP or PAHP. Medicaid populations are different from commercial groups and have unique needs. If states are allowed to use an MCO-wide accreditation standard, it may not be a reliable predictor of how well that MCO will be prepared to manage care for Medicaid populations, especially with regards to Long-term Services and Supports (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, CMS 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 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, for more detail.*

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:

To the extent that CMS permits states to deem compliance based on private accreditation by an authorized entity, the regulations must ensure that those private entities’ standards and measures are readily and publicly available at no or nominal cost. Alternatively, the 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.

²² 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).

CMS 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

CCD is concerned about §438.334(d) allowing MCOs, PIHPs, and PAHPs serving only dual eligibles to opt out of the Medicaid managed care quality rating system and instead utilize the MA five-star rating. The MA system lacks LTSS related quality measures. We recommend that plans opting for the MA five-star rating system still be held accountable for LTSS quality measures established in the 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, it is unclear what HHS means by “affordability” in paragraph (a)(2). Because out-of-pocket expenses for Medicaid beneficiaries do 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 is cheaper for the Medicaid program may rate equally to a slightly more expensive plan with better health outcomes. From the point of view of a beneficiary, the second plan would be the better choice, but the star rating system might not reflect that. We believe the term “efficiency” better addresses the triple aim of better care, better health outcomes, and affordability. We recommend that CMS delete

“affordability” as a component of the star rating system (unless 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. CMS 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.²³ 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.²⁴ 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.

Recommendation:

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

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.

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***

²³ See above, § 438.330(a)(2).

²⁴ 42 C.F.R. §§ 431.408 - 416.

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 CMS has proposed requiring states to include in their comprehensive quality strategy. We ask CMS 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 very positive changes for Medicaid EQR. We support the proposal to extend EQR to include PAHPs that contract with the state, to increase EQR availability, and especially the proposal to add a new mandatory EQR-related activity focusing on actively testing MCO, PIHP and PAHP managed care networks. On the other hand, HHS appears to have simultaneously weakened EQR through the broadening of the nonduplication provision in § 438.360 and the reduction of federal matching rates for EQR and EQR-related activities conducted on non-MCO managed care plans. We 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 approach. We do not agree with the proposed language that states should have sole discretion over whether EQR should be required for such PCCM entities. We believe the regulation should presume that PCCM entities with a financial stake in quality outcomes would be subject to EQR, and that the state should have to justify not requiring EQR for such PCCM entities to the Secretary. At the very least, we recommend amending the proposed language to clearly give the Secretary the option to require EQR for such entities.

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

Recommendations:

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.

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 in the EQR regulation.

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

Recommendations:

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.**"

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—

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.

§ 438.358 Activities related to external quality review

As Medicaid increasingly employs capitation and accountable care as the preferred payment model, robust, independent quality review becomes an even more critical component to counteract financial incentives to limit coverage of necessary care. To this end, we commend HHS for proposing to require EQR to include validation of provider network adequacy. The preface suggests this new EQR protocol will include direct testing methods such as secret shopper surveys, to validate network adequacy for MCOs, PIHPs, PAHPs and PCCM entities required to conduct EQR under § 438.350. The 2014 HHS Office of the Inspector General reports cited in the preamble demonstrate the efficacy and importance of directly evaluating provider networks for compliance, access and availability.²⁵ They plainly show that the “compliance reviews” normally conducted through EQR can be pro forma and have not effectively evaluated actual compliance in the area of network adequacy. Moreover, states that engage in direct testing of compliance, such as calling providers to assess availability and verify the accuracy of provider directories, or calling plan customer service to evaluate wait times and responsiveness, are far more likely to identify violations in access and timeliness standards.

We support HHS’ imposition of the requirement to validate network adequacy, but do not believe it goes far enough. As the OIG reports revealed, an absence of violations of requirements can indicate a weak and passive review process rather than exceptional plan performance. We believe it unlikely that managed care compliance problems are limited to provider networks. For this reason, we recommend that HHS expressly require direct testing in other compliance areas as well, including care coordination, utilization management, and service authorization. Under our recommendation, a state would have to conduct annual direct testing of at least a subset of managed care quality standards each year. This requirement would stand apart from the existing requirement to require comprehensive compliance review at least every three years. 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 profile, this oversight technique is important enough that it should be expressly described in the regulation itself. Second, HHS should clarify that the validation of network adequacy includes three interrelated but distinct components: network adequacy standards (which must include at least time and distance standards), timeliness and availability standards (described in detail in § 438.206) and the accuracy of provider directories (described in §438.10(h)). As currently written, the EQR would only have to validate State network adequacy standards required in § 438.68, and does not clearly encompass the other two fundamental components. HHS description of the proposed new EQR protocol does envision activities such as testing provider directories, but the preamble also appears to distinguish the requirements at § 438.206 from network adequacy standards when it claims that: “An assessment of compliance with § 438.206 (availability of services) would occur as part of the mandatory compliance review

²⁵ 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).

described in §438.358(b)(3).”²⁶ 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 two mandatory EQR activities. We believe a full review and accounting of grievances and appeals should be a mandatory EQR-related activity. Such a review can provide states with another mechanism to identify systemic issues and act upon them. Similarly, requiring states or EQROs to collect data directly from enrollees, in the form of focus groups or beneficiary surveys, will provide a useful cross check for broad-based CAHPS surveys and can help states directly evaluate a plan’s compliance with other standards, such as care coordination and utilization management. Such consumer surveys and focus groups are currently optional EQR related activities.

Recommendations:

Amend §438.358(b)(3) as follows, add new subparagraph (4) (renumbering (b)(4) to (b)(5), shift paragraph (c)(2) to a new paragraph (b)(6), and add new subparagraph (7):"

(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 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.

Amend paragraph (c) to conform with the above recommended changes as follows:

²⁶ 80 Fed. Reg. 31156.

(c)(2) Administration or validation of ~~consumer or~~ provider surveys of quality of care;

§ 438.360 - Nonduplication of mandatory activities

The major expansion of required Medicaid accreditation proposed in § 438.332 has serious implications for the EQR process. While we recognize the merit of minimizing unnecessarily duplicative oversight activities, the changes proposed for this section appear to directly contradict and undermine other proposed changes to strengthen the EQR process. The only example described in the preamble of how this new process would work frankly raises more questions than it answers.²⁷ We strongly oppose the proposed changes to the non-duplication provision, and recommend that HHS abandon its proposed expansion of the provision. At the very least, HHS must address the multiple concerns and apparent conflicts the proposed changes raise and ensure that the proposed expansion of private accreditation does not effectively replace independent EQR. These concerns include a lack of transparency, a potential for increased time lag for data, questions about the independence of validation tests from private accreditors, and concerns about the comparability of Medicaid with commercially-insured populations.

The proposed changes would expand the current nonduplication provision to allow states to use information from private accreditors in lieu of mandatory EQR-related activities for the validation of PIPs and performance measures. In previous rule-making that finalized the current regulations, HHS justified excluding these activities from the nonduplication provision because the private accreditation review often encompasses an MCO or PIHP's commercial lines of business.²⁸ 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.²⁹ 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, including timing. First, the preamble notes that states can use information from private accreditation within the previous three years in lieu of mandatory EQR activities.³⁰ 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.³¹ If the accreditation review covers data from a

²⁷ See 80 Fed. Reg. 31156-7.

²⁸ 68 Fed. Reg. 3603.

²⁹ *Id.*

³⁰ 80 Fed. Reg. 31157.

³¹ 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*

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.³²

The example of nonduplication described in the preamble raises additional concerns about how the state will apply the “substantially comparable” standard.³³ HHS suggests that an MCO, PIHP or PAHP with NCQA accreditation must have undergone a validation process for its HEDIS measures, and that if the accreditation review standards are “substantially comparable” to the standards laid out for that activity in the EQR protocols, then the state could use the data from the accreditation in lieu of conducting a separate EQR validation. But it is not clear what would happen if this same state requires other performance measures that are not part of HEDIS. For example, if the state includes LTSS or any other non-HEDIS measures, in its managed care contracts, the state should still be responsible for contracting with an EQRO to validate all the non-HEDIS measures it requires separately. If accreditation standards are hidden behind a paywall or a claim of “proprietary property,” advocates will have 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 § 438.354.³⁴ 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 impactful changes to EQR is the requirement that states incorporate direct testing into their EQR review. As noted above, we believe that the 2014 OIG reports on network adequacy reveal a major shortcoming of the current EQR compliance review process, and demonstrate the value of using direct testing to review MCO compliance with other Medicaid standards beyond network adequacy, such as care coordination, notice and due process, and utilization management. We strongly urge HHS to require states to

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>.

³² 80 Fed. Reg. 311282 [proposed § 438.364(b)].

³³ 80 Fed. Reg. 31156-57.

³⁴ 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>.

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

Recommendation:

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

§ 438.362 – Exemption from external quality review

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

§ 438.364 – External quality review results

We support the recommended additions that require EQR annual technical reports to include results from performance measures and from PIPs alongside the validation results. States are not currently required to report these results, though many already do. This change will make it easier to locate data by centralizing it in a single report that must be posted on the state Medicaid web site. 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: 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.

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 prior technical reports dating back at least five years or to the inception of the State's managed care program.*

§ 438.370 - Federal Financial Participation

HHS explains that it has reviewed the statutory language relating to the applicability of enhanced federal matching rates to EQR and EQR-related activities. Specifically, HHS is reinterpreting the statute to limit the enhanced 75% federal match to EQR activities for MCOs.³⁵ 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 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. 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 EQRO of PIHPs, PAHPs and some PCCM entities, we recommend that HHS maintain availability of enhanced match for EQR and EQR related activities for all the managed care plans subject to EQR.

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

Subpart F Grievance System

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. To this end, we recommend: Amend section (a) as follows:

(b) *Special requirements.* ...

(1) Acknowledge receipt of each grievance and appeal *within 3 calendar days.*

...

³⁵ 80 Fed. Reg. 31157-58.

(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*.

§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.

Amend subsections (b) and (c) 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 their right to request a State fair hearing to contest the service authorization decision as set forth in §438.408(2).

~~(de)~~ *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 longer than 2 calendar days after the disposition.**

...

~~(ef)~~ *Content of notice of appeal resolution.*

...

~~(fg)~~ *Requirements for State fair hearings.*

...

(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 so that there is no room for debate.

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.

Amend the regulation 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.

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, (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 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. The preamble’s statement of intent is clear, as was CMS employees’ explanation of the regulation in webinar sponsored by CMS to explain the regulations. Nevertheless, this aspect of the grievance and appeals proposed regulations is, without question, has generated the most discussion among legal advocates for Medicaid beneficiaries. 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.

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.

(a) *Definitions.* As used in this section—

Timely filings 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~~;

.....

(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*. To ensure this fairness, the state fair hearing needs to occur de novo. We recommend:

Add a new 42 C.F.R. § 431.234 as follows:

§ 431.233 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 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 serviced, 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.

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** reverses 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*

CCD appreciates the opportunity to provide comments to the NPRM. If you have questions or need additional information please contact Rachel Patterson (rpatterson@christopherreeve.org) or Julie Ward (ward@thearc.org).

On behalf of:

ACCSES
American Association on Health and Disability
American Network of Community Options and Resources
American Occupational Therapy Association
American Speech-Language-Hearing Association

Association of University Centers on Disabilities
Autism Speaks
Bazelon Center for Mental Health Law
Brain Injury Association of America
Christopher & Dana Reeve Foundation
Disability Rights Education and Defense Fund
Epilepsy Foundation
Family Voices
Lutheran Services in America Disability Network
National Alliance on Mental Illness
National Association of Councils on Developmental Disabilities
National Association of State Head Injury Administrators
National Council on Aging
National Down Syndrome Congress
National Multiple Sclerosis Society
National Respite Coalition
The Arc of the United States
United Spinal Association