HSAG HEALTH SERVICES ADVISORY GROUP

Ware, Jerry
Federal Register Summary of Changes

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Overview:			
The Centers for Medicare & Medicaid Services (CMS) proposes to align standards for Medicaid managed care with those in Medicare Advantage and commercial coverage, where appropriate, and to align Children's Health Insurance Program (CHIP) managed care standards with those of the Marketplace and Medicaid, where practical, to ensure consistency across programs. Not all of the Medicaid managed care provisions are easily applied to the CHIP program; the scope of the CHIP proposed regulation revisions is narrower than the proposed revisions to the Medicaid managed care regulations. The following sections contain proposed changes to the federal regulations at 42CFR438. Associated citations and references to the current regulations are also provided.			
General:			
CMS proposes changes to how the medical loss ratio (MLR) is calculated and changes to the actuarial soundness formulas. The proposed rule would require that both Medicaid and CHIP managed care plans calculate their MLR according to standards that are similar to Medicare Advantage and the private market, while accounting for unique characteristics of the Medicaid or CHIP programs. Changes include: ♦ MLR of at least 85 percent—actuarially sound rates to be set. ♦ Clarifications of calculations for MLR—expenses for program integrity activities could be included in the numerator for the MLR calculation. ♦ Clarifications related to capitation rates, especially related to services provided while in an institution of mental disease (IMD). ♦ Minimum recordkeeping requirements of six years.	♦ 438.4–438.8, pages 21257–31263	♦ Preamble, pages 31107–31113	♦ New
External Quality Review Processes:			
♦ CMS proposes that information from Medicare or private accreditation reviews is a permissible source of information for use in the external quality review (EQR), with results included in the EQR technical report (The new fourth mandatory activity is not included [i.e., may not be deemed in this manner—page 31157]).	♦ New Subpart E (Several Quality Program requirements moved from	♦ Preamble, pages 31151–31152	♦ New (Subpart E previously reserved)

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	Subpart D), page 31278 ♦ 438.350, page 31281		
♦ If the state chooses to use information obtained from a Medicare or private accreditation survey to provide information otherwise obtained from mandatory activities, this strategy may now be used for three mandatory activities (compliance, performance improvement projects [PIPs], and performance measure validation [PMV]). Previously, this strategy could only be used for monitoring compliance. In its comprehensive quality strategy, a state must identify the mandatory activities for which it has exercised this option and explain its rationale for why these activities are duplicative.	♦ 438.360(b)(2) and (c), page 31282	♦ Preamble, page 31157	♦ 438.360, page 31282
♦ Modification of who may conduct EQR-related activities—"other entities in addition to or instead of an EQRO that is not a managed care organization (MCO), prepaid inpatient health plan (PIHP), or prepaid ambulatory health plan (PAHP) may conduct EQR-related activities" (i.e., deeming could also apply to PMV and PIP activities—could previously, but would not be extended to the fourth mandatory activity—Validation of Network Adequacy). ♦ *Note: In its comprehensive quality strategy, the state must identify the mandatory activities for which it has exercised this option and explain its rationale for why these activities are duplicative. (This element has not changed.)*	♦ 438.356, page 31281 (not yet written here)	♦ Preamble, pages 31156–31157	♦ 438.356, page 3636 ♦ (Federal Register January 24, 2003)
♦ CMS proposes revising the definition of an "external quality review organization" (EQRO) to specify that an entity would not be considered an EQRO if it has not yet entered into a contract with a state even if it meets all qualifications of an EQRO.	♦ Definition of EQRO at 438.320 (proposed change not yet written here)	♦ Preamble, page 31150	♦ 438.320, page 3635 ♦ (Federal Register January 24, 2003)

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♦ Addition of a fourth mandatory EQR activity: to validate MCO, PIHP, and PAHP network adequacy during the preceding 12 months. States would conduct this activity for each MCO, PIHP, and PAHP (new EQR protocol pending).	♦ 438.358(b)(4), page 31281	♦ Preamble, pages 31156 and 31187	♦ 438.358, page 3636 (Federal Register January 24, 2003)
♦ Expansion of technical report requirements: ▪ Additional requirement for EQR technical report to include *performance* information related to mandatory activities and related recommendations (not just validation). ▪ Addition of recommendations for how states can target the goals and objectives to better support improvement in the quality, timeliness, and access to healthcare services furnished. ▪ Addition that "states may not substantively revise the content of the final EQR technical report without evidence of error or omission."	♦ 438.364(a)and (b), page 31282—31283	♦ Preamble, page 31157	♦ 438.358, page 3637 (Federal Register January 24, 2003)
♦ Annual technical reports for all states are due no later than April 30 each year, and it is proposed that the annual EQR technical report must address data collected in the previous 15 months.	♦ 438.364(b), page 31282	♦ Preamble, page 31199	♦ 438.364, page 3637 (Federal Register January 24, 2003)
Changes to requirements related to the State's Quality Strategy/State Responsibilities:			
♦ CMS proposes application of standards and EQR processes to PAHPs, with performance results available in the EQR technical report. Non-emergency medical transportation (NEMT) PAHPS are exempt from EQR and specified requirements. NEMT exemptions: ▪ NEMTs are not required to have an internal grievance/appeal system. NEMT PAHP members have direct access to the state fair hearing (SFH) process. ▪ Physician incentive plans	♦ PAHPS: 438.3–438.8, pages 31256–31260; ♦ NEMT PAHPs: 438.9, page 31263; ♦ Standards that apply to PAHPs:	♦ Preamble, pages 31103, 31149, and 31155	♦ New

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▪ Advance directives ▪ Long-term services and supports (LTSS) requirements ▪ Mental Health Parity and Addiction Equity Act (MHPAEA) ▪ Actuarial soundness requirements at 438.4 ▪ Information requirements in 438.10 ▪ Provision against provider discrimination at 438.12 ▪ State responsibility provisions at 438.56, 438.58, 438.60, and 438.62 ▪ Provisions on enrollee rights and protections in Subpart C (except for 438.110 and 438.114) ▪ PAHP standards in 438.206(b)(1), 438.210, 438.214, 438.224, 438.230, and 438.242 ▪ Enrollee's right to a SFH ▪ Prohibitions against affiliations with debarred or excluded individuals at 438.610	▪ 438.10–438.14 ▪ 438.100–438.116 ▪ 438.206–438.242 ▪ 438.310–438.334 ▪ 438.400–438.424 ▪ 438.604–438.610		
♦ Addition of the definition of "primary care case management (PCCM) entity"; state assessment of performance would include assessment of PCCM entities and must be included in the Quality Strategy (contracts with PCCMs must be submitted to CMS). Application of standards to PCCM entities (EQR processes and federal financial participation [FFP] apply in some circumstances).	♦ State contract requirements: 438.3, page 31257 ♦ Quality Strategy requirement: 438.340(e), page 31280 ♦ PCCM: 438.350 and 438.358 (may apply based on 438.3(r), page 31257)	♦ PCCM definition Preamble, page 31163	♦ New

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	♦ Assessment of PCCM entities: 438.3(r), page 31257 ♦ Standards that apply to PCCM entities: ▪ 438.10 ▪ 438.14 ▪ 438.100 ▪ 438.604 ▪ 438.608(b) ▪ 438.610		
♦ States must review and approve managed care plans once every three years using standards as stringent as those used by accrediting organizations (or use evidence that the plan has obtained accreditation by a CMS-recognized entity).	♦ Approval of MCOs, PIHPs, and PAHPs: 438.310(b)(2) and 438.332(a), pages 31278–31280.	♦ Preamble, page 31151	♦ New
♦ States must develop a quality rating system. Results must be prominently displayed online (published annually).	♦ 438.334, page 31280	♦ Preamble, pages 31152–31153	♦ New
♦ Include measurement of quality and appropriateness of care furnished to enrollees receiving LTSS provided by MCOs, PIHPs, and PAHPS in the Quality Strategy.	♦ 438.330(b)(5), page 31280	♦ Preamble, pages 31138 and 31144	♦ New
♦ The state must require that any MCO, PIHP, or PAHP contract that includes providing LTSS, the MCO, PIHP, or PAHP must establish and maintain a member advisory committee.	♦ 438.110, page 31274	♦ Preamble, page 31144	♦ New

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♦ State quality requirements will be extended to all state Medicaid programs (previously only those states contracting with MCOs, PIHPs, or PAHPs) (would include CHIP, Managed Long Term Services and Supports [MTLSS], PCCM, and fee-for-service [FFS]).	♦ 431 Subpart I: 431.500 and 431.502	♦ Preamble, page 31153	♦ 438.202 and 438.204, pages 41105–41106
♦ Update the quality strategy once every three years (was previously periodically).	♦ 431.504(b), page 31253	♦ Preamble, page 31154	♦ New
♦ States must publish quality metrics and technical reports (see p. 31157) on the required website. In further support of improved clarity, CMS proposes moving the evaluation of the effectiveness of the quality strategy into a new paragraph (b)(1). In paragraph (b)(2), CMS proposes that states make the results and findings of this effectiveness evaluation publicly available on the state's Medicaid website.	♦ 438.364(b)(2), page 31282	♦ Preamble, pages 31157–31160	♦ New. No previous content requirement for a state website in 438 or 431
♦ Expansion of minimum elements of a state's quality strategy.	♦ 431.500,502,504, and 506; 438.340, page 31280	♦ Preamble, pages 31154—31155	♦ 438.204, page 41106
♦ Addition of a requirement for states to perform readiness reviews (including readiness to implement LTSS) at least three months prior to the effective date of the new MCO, PIHP, or PAHP contract (and submit to CMS). Components of readiness reviews are specified. Significant number of additions and more specificity to ongoing monitoring requirements (specifies that this monitoring is a state activity). Updated specific requirements for state monitoring of MCOs, PIHPs, and PAHPs.	♦ 438.66(d)(2), page 31270	♦ Preamble, page 31144; 31158	♦ New
♦ States must develop and enforce network adequacy standards (including time and distance standards, and the ability of providers to ensure physical access, accommodations, accessible equipment availability, and access for those with limited English proficiency [LEP]).	♦ 438.68, page 31271	♦ Preamble, pages 31144–31147	♦ New
♦ States must provide an annual program assessment to CMS (must be posted on the website and provided to the Medical Advisory Committee).	♦ 438.66(e), page 31271	♦ Preamble, page 31159	♦ New

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♦ Each state must address in the Quality Strategy how it will assess and improve the quality of healthcare and services furnished to all CHIP enrollees.	♦ 457.760, page 31293 and 457.1240(e), page 31296	♦ Preamble, page 31174	♦ New
Definitions			
♦ Added: Definition of "access" (as it pertains to EQR): 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.	♦ 438.320, page 31279	♦ Preamble, pages 31149–31150	♦ New
♦ Updated: Definition of "quality": the degree to which an MCO, PIHP, or PAHP increases the likelihood of desired health outcomes of its enrollees through its structural and operational characteristics and through the provision of health services that are consistent with current professional knowledge (added that is evidence-based and supported by current science).	♦ 438.320, page 31279	♦ Preamble, page 31150	♦ 438.320, page 3835 (Federal Register January 24, 2003)
♦ Clarified definition of "EQRO": An entity must hold an active contract with a state to be considered an EQRO.	♦ 438.320, page 31279 (proposed, not yet written here).	♦ Preamble, page 31150	♦ 438.320, page 3835 (Federal Register January 24, 2003)
♦ Added definition of "readily accessible"—to clarify the parameters for the provision of electronic information (Section 508 compliant).	♦ 438.10(a), page 31263	♦ Preamble, page 31159	♦ New
♦ Propose to amend the definition of "prevalent" to clarify that the non-English languages that are relevant are those spoken by a significant number or percentage of potential enrollees and enrollees in the state that are limited English proficient, consistent with standards used by the Office for Civil Rights in enforcing antidiscrimination provisions related to individuals with limited English proficiency.	♦ 438.10(a), page 31263	♦ Preamble, page 31159	♦ 438.10, page 41099

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♦ Propose to clarify "primary care case manager" (PCCM) to mean a physician, a physician group practice, or, as a state option, any of the following: ▪ A physician assistant. ▪ A nurse practitioner. ▪ A certified nurse-midwife.	♦ 438.2, page 31255	♦ Preamble, page 31164	♦ 438.2, page 41097
♦ Added definition of "PCCM entity" to mean an organization that provides any of the following functions, in addition to PCCM services, for the state: ▪ Provision of intensive telephonic or face-to-face case management, including operation of a nurse triage advice line. ▪ Development of enrollee care plans. ▪ Execution of contracts with and/or oversight responsibilities for the activities of FFS providers in the FFS program. ▪ Provision of payments to FFS providers on behalf of the state. ▪ Provision of enrollee outreach and education activities. ▪ Operation of a customer service call center. ▪ Review of provider claims, utilization, and practice patterns to conduct provider profiling and/or practice improvement. ▪ Implementation of quality improvement activities including administering enrollee satisfaction surveys or collecting data necessary for performance measurement of providers. ▪ Coordination with behavioral health systems/providers. ▪ Coordination with LTSS systems/providers.	♦ 438.2, page 31255	♦ Preamble, page 31163–31164	♦ New
♦ Changed definition of "rural area" for purposes of the state option to contract with one MCO, PIHP, PAHP, or PCCM under mandatory Medicaid managed care programs. As used in this paragraph, a "rural area" is any county designated as "micro," "rural," or "County with Extreme Access Criteria (CEAC)" in the Medicare Advantage Health Services Delivery (HSD) Reference file for the applicable calendar year.	♦ 438.52(b)3), page 31267	♦ Preamble, page 31165	♦ 438.52, page 41102

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♦ Capitation payment: CMS proposes to remove the word "medical" that modifies "services" in recognition of proposed changes throughout this proposed rule to incorporate managed LTSS in part 438.	♦ 438.2, page 31254	♦ Preamble, page 31169	♦ 438.2, page 41096
♦ Comprehensive risk contracts: CMS proposes to add that the contract is "between the State and an MCO." This proposed modification would clarify that only MCOs can have comprehensive risk contracts and it is also appropriate to identify the parties to the contract.	♦ 438.2, page 31254	♦ Preamble, page 31169	♦ 438.2, page 41096
♦ Healthcare professional: CMS proposes to revise the definition for "healthcare professional." For purposes of section 1932(b)(3)(C) of the Social Security Act (the Act), "healthcare professional" is defined as a "physician . . . or other healthcare professional if coverage for the professional's services is provided under the contract" and sets forth a minimum list of healthcare professionals that may provide services covered under the managed care. CMS proposes to include language from the statutory definition in the regulation that the physician's or provider's services are covered under the contract in the regulatory definition of "healthcare professional" to clarify that providers of services other than medical services, such as LTSS, would be included in this definition. CMS also proposes to delete the list of professionals in section 1932(b)(3)(C) of the Act from the regulatory definition of "healthcare professional" because the list was not intended to be exclusive and inclusion of this list in the regulatory definition does not clarify the intent for this definition.	♦ 438.2, page 31255	♦ Preamble, page 31169	♦ 438.2, page 41096
♦ Added a definition of "managed care program" to mean a managed care delivery system operated by a state as authorized in the 1915(a) or (b), 1932(a), or 1115(a) of the Act.	♦ 438.2, page 31255	♦ Preamble, page 31169	♦ New
♦ Added a definition of "network provider" to mean a healthcare professional, group of healthcare professionals, or entity that receives Medicaid funding directly or indirectly to order, refer, or render covered services as the result of the state's arrangement with an MCO, PIHP, or PAHP.	♦ 438.2, page 31255	♦ Preamble, page 31169	♦ New

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♦ Revised definitions related to Coverage and Authorization: ▪ Replaced the term "action" with "adverse benefit determination." ▪ Revised the definition of "appeal" to clarify that an appeal is a review by the MCO, PIHP, or PAHP. ▪ Revised the definition of "grievance" to replace the term "action" with "adverse benefit determination" and add examples of possible grievances. ▪ Added a definition for "grievance system." ▪ Removed SFH from the definition of "grievance system," as SFH is defined separately in Part 431, Subpart E.	♦ 438.400(b), page 31283	♦ Preamble, pages 31103–31104	♦ 438.400, page 41109
♦ Revised the definition of "choice counseling" and added a requirement for states to provide choice counseling for any potential enrollee.	♦ 438.2, page 31254 ♦ 438.71(c), page 31272	♦ Preamble, page 31136	♦ 438.810, page 41115
♦ Added a definition of "LTSS" as services and supports provided to enrollees of all ages who have functional limitations and/or chronic illnesses that have the primary purpose of supporting the ability of the enrollee to live or work in the setting of his or her choice, which may include the individual's home, a provider-owned or controlled residential setting, a nursing facility, or other institutional setting. ▪ Examples include home and community-based services delivered through a 1915(c) waiver, section 1915 (i), or section 1915(k) state plan. ▪ Individuals with chronic illness may include individuals with mental health conditions and substance abuse disorders.	♦ 438.2, page 32155	♦ Preamble, pages 31141–31143	♦ New
♦ CMS proposes to define "medically necessary services" by adding that such criteria must meet the requirements for providing Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) for individuals under the age of 21.	♦ 438.210(a)(5), page 31276	♦ Preamble, pages 31138–31139	♦ 438.210, page 41107

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♦ Clarified/expanded the definition of "grievance" to specify that it includes an enrollee's right to dispute an extension of time proposed by the MCO, PIHP, or PAHP to make an authorization decision. Also, CMS proposes to separately define "grievance system."	♦ 438.400(b)(6), page 31283	♦ Preamble, page 31104	♦ 438.400(b)(6), page 41110
Member Information			
♦ States will be required to operate a website. An updated list of documents required on the state website is in the new regulation.	♦ 438.10(b)(3), pages 31263–31265	♦ Preamble, page 31160	♦ New
♦ CMS proposes to permit both states and managed care plans to make beneficiary information available in electronic form (if conditions are met), and added standards for providing electronic information. Electronic information must be compliant with language, formatting, and accessibility standards (Section 508 compliant).	♦ 438.10(c)(6), pages 31263–31265	♦ Preamble, pages 31159–31160	♦ New
♦ CMS proposes adding new standards for language and format that apply to the state, MCOs, PIHPs, and PAHPs. Standards include: ▪ Font size no smaller than 12 point. ▪ All materials must include tag lines in each prevalent non-English language that explain the availability of written materials in those languages and availability of oral interpretation (which includes auxiliary aids) for understanding the materials. ▪ All materials must include a large print tag line that includes information about how to request auxiliary aids and services and alternative formats. ▪ Large print copies must be no smaller than 18 point. ▪ All written materials must be made available in alternative formats, and auxiliary aids and services must be made available upon request.	♦ 438.10(d), page 31263	♦ Preamble, page 31160	♦ New

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♦ States will be required to develop standardized managed care definitions and terminology. States will also be required to develop model enrollee handbooks and notices. ▪ These materials must have the ability to be printed from the website. ▪ The MCO, PIHP, or PAHP must provide materials in paper at no cost within five calendar days of the request.	♦ 438.10(c)(4) and 438.10(c)(6)(v), page 31263	♦ Preamble, page 31160	♦ New
♦ CMS proposes expanding the documents considered as vital documents which must be translated into a non-English language of each group considered limited English proficient and likely to be affected by the program or activity. Vital documents will include at least: ▪ Provider directories. ▪ Member handbooks. ▪ Appeal and grievance notices. ▪ Other notices critical to obtaining services.	♦ 438.10, pages 31263–31265	♦ Preamble, page 31160	♦ New
♦ Day-to-day communications with members may be electronic and could include email (if the enrollee consents) or website postings, but health plans must notify members of availability in paper form and through auxiliary aids and services at no cost.	♦ 438.10, pages 31263–31265	♦ Preamble, page 31161	♦ New
♦ Minimum standards for enrollee handbooks are outlined.	♦ 438.10, pages 31263–31265	♦ Preamble, page 31161	♦ New
♦ Minimum standards for provider directories are outlined. Additional requirements include: ▪ Provider's group/site affiliation. ▪ Website url (if available). ▪ Cultural/linguistic capabilities. ▪ Accessibility for enrollees with physical disabilities. ▪ Availability on the MCO, PIHP, and PAHP websites. ▪ Website version must be machine readable (Section 508 compliant).	♦ 438.10, pages 31263–31265	♦ Preamble, page 31162	♦ New

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♦ Standards for updating provider directories: ▪ Paper copies updated at least monthly. ▪ Electronic directories updated at least three business days of receiving updated information.	♦ 438.10, pages 31263–31265	♦ Preamble, page 31162	♦ New
♦ Thirty-day advance notice of significant change in information provided in the member handbook may be electronic.	♦ 438.10(g)(3), pages 31263–31265	♦ Preamble, page 31162	♦ 438.10, page 41100
♦ Drug formulary must include all covered medications (generic and brand name), have the tier level for each, and be posted on the MCO, PIHP, or PAHP website in machine readable format.	♦ 438.10(i)	♦ Preamble, page 31162	♦ New
Coverage and Authorization of Services			
♦ Authorization periods for enrollees with ongoing and chronic care needs, including LTSS, should reflect the ongoing needs for these services. ▪ May include the authorization of nonclinical services. ▪ MCOs, PIHPs, and PAHPs must employ authorization strategies that adequately support individuals with ongoing or chronic conditions who require LTSS.	♦ 438.210(b), page 31276	♦ Preamble, page 31138	♦ New
♦ Denial of the enrollee's right to receive (upon request and free of charge) reasonable access to and copies of all documents, records, and other information relevant to the enrollee's claim for benefits constitutes an adverse benefit determination.	♦ 438.404(b)(2), page 31283	♦ Preamble, page 31104	♦ New
♦ Clarification: Replace "expedited resolution" with "expedited appeal process" (proposed).	♦ 438.410, page 31285	♦ Preamble, page 31105	♦ 438.410, page 41111
♦ Clarification: MCOs, PIHPs, and PAHPs may not extend the time frames at 438.210 (authorization) without meeting the requirements (need for additional information and in the enrollee's interest).	♦ Language in Preamble only	♦ Preamble, page 31105	♦ New

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Grievance System			
♦ A member must exhaust the internal MCO, PIHP, or PAHP appeal process before accessing the state fair hearing.	♦ 438.402(c), pages 31283 and 31285	♦ Preamble, page 31104	♦ 438.402, page 41110
♦ Removed the standard for the enrollee's written consent for the provider to file an appeal on an enrollee's behalf.	♦ 438.402(c)(1)(2)	♦ Preamble, page 31106	♦ 438.402, page 41110
♦ Clarified that a member may file a grievance with the MCO, PIHP, or PAHP at any time (rather than imposing a time frame).	♦ 438.402(c)(2), page 31283	♦ Preamble, page 31104	♦ 438.402, page 41110
♦ Deleted the state's option to choose the appeal filing time frame (from 20 to 90 days and to set the timing standard for filing appeals at 60 calendar days).	♦ 438.402(c)(2), page 31283	♦ Preamble, page 31104	♦ 438.402, page 41110
♦ Set the time frame for requesting a state fair hearing at 120 calendar days from the date of the MCO/PIHP/PAHP notice of appeal resolution.	♦ 438.408(f)(2), page 31285	♦ Preamble, page 31106	♦ 438.408, page 41111
♦ Changes to handling of grievances (for clarity): ▪ Grievance and appeal decisions must take into consideration all comments, documents, records, and other information submitted by the enrollee or representative without regard to whether such information was submitted or considered in the initial adverse benefit determination. ▪ Requirement to provide the enrollee or representative (free of charge and sufficiently in advance of the resolution time frame for appeals) the enrollee's case file, including medical records, other documents and records, and any new or additional evidence considered, relied upon, or generated by the MCO, PIHP, or PAHP in connection with the appeal of an adverse determination (previous rule was to provide the opportunity to review rather than provide the documents). ▪ Add "testimony" and reword to say "testimony, or legal facts and arguments" to replace "allegations of fact or law." ▪ "Sufficiently in advance" instead of "before and during."	♦ 438.406(b)(2)(c)(iii), page 31284	♦ Preamble, page 31105	♦ 438.406, page 41110

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♦ Addition of auxiliary aids to assistance to definition of "reasonable assistance" in completing forms and taking procedurals steps to handle grievances and appeals.	♦ 438.406(a), page 31284	♦ Preamble, page 31105	♦ 438.406, page 41110
♦ Addition that individuals who are subordinates of individuals who were involved in any previous level of review may not resolve the grievance or the appeal.	♦ 438.406(b)(2)(i), page 31284	♦ Preamble, page 31105	♦ 438.406, page 41110
♦ Changes in the time frame for taking action on appeals. The time frame is still established by the state but may not exceed: ▪ Standard appeals = 30 calendar days (was 45 calendar days). ▪ Expedited appeals = 72 hours (was three working days). ▪ Expedited SFH remains at three working days—page 31106.	♦ 438.408(b), page 31284	♦ Preamble, page 31105	♦ 438.408, page 41110
♦ CMS proposes to change the requirements for notifying members when extending resolution time frames for grievances and appeals; added the requirement to make reasonable efforts to provide the enrollee prompt, oral notice of the delay.	♦ 438.408(c)(2)(i), page 31284	♦ Preamble, page 31105	♦ 438.408, page 41110
♦ Grievance and appeal notices ensure "meaningful access" for people with disabilities (i.e., Section 508 compliant) by meeting the language and format requirements of 438.10. (See definition above for "readily accessible.")	♦ 438.408(d), page 31284	♦ Preamble, page 31106	♦ 438.408, page 41110
♦ Related to the continuation of services that have been proposed to be terminated, suspended, or reduced: the MCO, PIHP, or PAHP may not recoup the cost of those services that were continued when the final decision is adverse to the enrollee *if* the state does not follow the same practice for FFS Medicaid enrollees.	♦ 438.420(d), page 31285	♦ Preamble, page 31106	♦ 438.420, page 41111
♦ Information about the grievance system to providers and subcontractors (clarification and expanded).	♦ 438.414, page 31285 ♦ See also 438.10(g)(xi) page 31265	♦ Preamble, page 31106	♦ 438.414, page 41111

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♦ Grievance system record-keeping: ▪ Minimum standards set for types of information required to be documented. Required documentation includes: • Reason for the appeal/grievance. • Date received. • Date of each review. • Resolution at each level. • Date of resolution. • Name of the enrollee. ▪ State must review as part of ongoing monitoring. ▪ Accessible to CMS upon request.	♦ 438.416, page 31285	♦ Preamble, pages 31106–31107	♦ 438.416, page 41111
♦ Application of 438.420 to managed LTSS.	♦ 438.420, page 31285	♦ Preamble, page 31139	♦ New
♦ Expedited authorization determinations to be made within 72 hours (rather than three working days).	♦ 438.404(c)(6), page 31284 ♦ See also 438.210(d)(2)	♦ Preamble, page 31139	♦ 438.408, page 41111
♦ CMS proposes to revise the current rule so that the MCO, PIHP, or PAHP must effectuate a reversal of an adverse benefit determination and authorize or provide such services no later than 72 hours from the date it receives notice of the adverse benefit determination being overturned (was previously "as expeditiously as the enrollee's health condition requires").	♦ 438.424(a), page 31285	♦ Preamble, page 31107	♦ 438.424, page 41112
Availability and assurance of adequate capacity			
♦ Expanded requirements for assurance of providers/adequate access for limited-English proficient enrollees and enrollees with mental/physical disabilities.	♦ 438.206(c)(2)–(3), page 31275	♦ None	♦ New
♦ Documentation of adequate capacity must be submitted at the time of entering into a contract with the state and annually (annual submission is new).	♦ 438.207(c), page 31275	♦ Preamble, page 31148	♦ 438.207, page 41106

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Care Coordination Activities			
♦ The state must have in place a transition of care policy for individuals moving to managed care from FFS, or from one MCO, PIHP, PAHP, or PCCM entity to another. ▪ States must also include a transition of care policy standard in their contracts with MCOs, PIHPs, and PAHPs.	♦ 438.62(b), page 31270	♦ Preamble, page 31139	♦ New
♦ Ongoing source of "primary care": The word "primary" was removed to ensure each enrollee receives access to an ongoing source of care appropriate to his or her needs, regardless of whether the service provider is considered a primary care provider. ♦ Removed the words "health care" to explicitly recognize that MCOs, PIHPs, and PAHPs may coordinate not only healthcare services but a full range of community-based support services to provide services in the most integrated setting to enrollees. ♦ Expanded care coordination requirements to all enrollees.	♦ 438.208(b), page 31275	♦ Preamble, page 31140	♦ 438.208, page 41107
♦ Each MCO, PIHP, and PAHP will make a best effort to complete an initial health risk assessment within 90 days of the effective date of enrollment for all new enrollees.	♦ 438.208(b)(3), page 31276	♦ Preamble, page 31140	♦ New
♦ All providers, practitioners, and suppliers maintain and share an enrollee health record.	♦ 438.208(b)(5), page 31276	♦ Preamble, page 31140	♦ New
♦ All managed LTSS, regardless of underlying authority, must operate in accordance with 10 key principles (newly developed). http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Delivery-Systems/Downloads/1115-and-1915b-MLTSS-guidance.pdf (and Preamble, pages 31141–31143). Amending applicable citations to reflect the 10 key principles.	♦ Standards that apply to MLTSS: ▪ 438.10 ▪ 438.66 ▪ 438.68 ▪ 438.70 (Stakeholder engagement) ▪ 438.110	♦ Preamble, pages 31141–31143	♦ New

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	▪ 438.206–438.208 ▪ 438.214 ▪ 438.330 ▪ 438.816		
♦ CMS proposes a requirement for identification, assessment, and treatment/service planning through a person-centered planning process, for individuals receiving LTSS who are enrolled in an MCO, PIHP, or PAHP.	♦ 438.208(c)(3), page 31276	♦ Preamble, page 31143	♦ New
Subcontractual Relationships and Delegation			
♦ Added clarifying language specifying that the standards apply to all contracts and written arrangements that an MCO, PIHP, or PAHP has with any individual or entity that relates directly or indirectly to the performance of obligations under the contract. ▪ Revised language: "delegated activities, obligations, and responsibilities" to clarify that the Subcontracts and Delegation standards are applicable to all written arrangements, rather than just administrative delegates.	♦ 438.230(a), page 31277	♦ Preamble, page 31127	♦ 438.230, page 41108
QAPI			
♦ Subpart D renamed from "Quality Assessment and Performance Improvement" to "MCO, PIHP, and PAHP standards. Addition of Subpart E—Quality Measurement and Improvement: External Quality Review," to more accurately describe MCO, PIHP, and PAHP activities and EQR. (Removal, therefore, of previous 438.200, 438.202, 438.218, and 438.226 as these standards now exist elsewhere in the new standards.)	♦ Subpart D, page 31275. ♦ Subpart E, page 31278	♦ Preamble, page 31149	♦ Subpart D, page 31105. No previous Subpart E.
♦ New regulations would allow CMS to specify performance measures and PIP topics.	♦ 438.330(a)(2), page 31279	♦ Preamble, page 31150	♦ Former QAPI 438.240, page 41109 (CMS specify = new).

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♦ Addition of a standard stating that MCOs, PIHPs, and PAHPs participate in efforts by the state to prevent, detect, and remediate critical incidents that are based, at a minimum, on the requirements of the state for home and community-based waiver programs.	♦ New 438.330(b)(6)	♦ Preamble, page 31144	♦ Previous QAPI standards were at 438.240 (this element is new).
♦ MCO, PIHP, and PAHP quality systems should include MLTSS-specific quality elements and mechanisms to assess the quality and appropriateness of care provided to LTSS enrollees. CMS proposes that MCOs, PIHPs, and PAHPs compare LTSS services that an individual was receiving with those included in the individual's LTSS treatment plan.	♦ 438.330(c)(4), page 31279	♦ Preamble, pages 31144–31145	♦ New
♦ MCO, PIHP, and PAHP quality programs must include PIPs that focus on both clinical and nonclinical areas. The word "both" was added, which may indicate that more than one PIP is required at a time. The Preamble states, "We assume that each MCO/PIHP will conduct at least 3 performance improvement projects."	♦ 438.330(d), pages 31279–31280	♦ Preamble, page 31198	♦ 438.240, page 41109
Program Integrity			
♦ States must enroll all ordering and referring physicians or other professionals as participating providers (and thus screen them according to the required screening process). ▪ Applies to PCCMs and PCCM entities. ▪ States must enroll all network providers of MCOs, PIHPs, and PAHPs that are not otherwise enrolled with the state to provide services to FFS Medicaid enrollees (would not obligate the provider to render services to FFS enrollees). ♦ Unless the state includes specific requirements in managed care contracts, this would relieve MCOs, PIHPs, and PAHPs from administrative burden and duplication by having that function performed by the state (or Medicare for dually participating providers).	♦ 438.608(b), page 31287	♦ Preamble, page 31127	♦ New

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♦ States will be required to review ownership and control disclosures submitted by MCOs, PIHPs, PAHPs, and PCCM entities and any subcontractors and conduct federal database checks to determine exclusion status of the entity and any person with ownership or control interest (including the agent or managing employees): ▪ At the time of entering into the contract. ▪ No less than monthly thereafter.	♦ 438.602(c), page 31286	♦ Preamble, page 31128	♦ New
♦ States will be required to receive and investigate information from whistleblowers.	♦ 438.602(f), page 31286	♦ Preamble. page 31128	♦ New
♦ States will be required to post on the website (or otherwise make available) the MCO, PIHP, PAHP, or PCCM entity contract and results of any applicable program integrity information and the results of any audits performed (related to 438.604).	♦ 438.604(g), pages 31286–31287	♦ Preamble, page 31128	♦ New
♦ Specification of what must be included in an MCO's, PIHP's, or PAHP's program integrity/compliance program (expanded).	♦ 438.608, page 31287	♦ Preamble, pages 31129–31131	♦ 438.608, page 41112
♦ "Prohibited Affiliations with Individuals…" (Section title) renamed "Prohibited Affiliations" to clarify that the regulations also apply to entities.	♦ 438.610, page 31288	♦ Preamble, page 31131	♦ 438.610, page 41112
CHIPRA (pages 31295–31297)			
Standards at 42CFR438.56, 438.68, 438.100, 438.102, 438.104, 438.106, 438.114, 438.207, 438.208, 438.210 438.214, 438.230, 438.236, 438.242, 438.330 438.334, 438.340, 438.350, 438.352, 438.354, 438.356, 438.358, 438.364, 438.400–438.424, and 438.600–438.610 apply to CHIP members with the exceptions noted below: ♦ 438.210(a)(5)—specification of what constitutes medically necessary services in a manner that is no more restrictive than that used in the state Medicaid program—**DOES NOT APPLY TO CHIP**. ♦ 438.210(d)—standard and expedited authorization decision and extension time frames—**DO NOT APPLY TO CHIP.** Time frames specified at 42CFR457.1160 apply (this is confusing—it seems to be a different type of review referenced in 457.1160). ♦ 438.330(d)(3)—options for organizations serving Medicare/Medicaid dually eligible individuals—**DOES NOT APPLY TO CHIP.** ♦ 438.334(d)—pertaining to dual eligible—**DOES NOT APPLY TO CHIP.**			

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♦ 438.360—nonduplication of mandatory activities—**DOES NOT APPLY TO CHIP.** ♦ 438.362—options for exemption from EQR—**DOES NOT APPLY TO CHIP.** ♦ 438.420—Continuation of previously authorized services during an appeal or SFH—**DOES NOT APPLY TO CHIP.** **All other CHIP standards can be found at 42CFR Part 457.**			