On May 6, 2016, the Centers for Medicare & Medicaid Services (CMS) published a Final Rule implementing changes related to a broad range of managed care issues under Medicaid and CHIP. The following are key provisions of the rule.

I. Medicaid Managed Care

Marketing (§438.104)

The Final Rule amends the definition of “marketing” to exclude communications to a Medicaid beneficiary about a qualified health plan (QHP) on a Health Insurance Exchange from the issuer of the QHP, even if the issuer also operates a Medicaid health plan. This allows, for example, the issuer to provide information on the QHP to Medicaid plan enrollees who could potentially enroll in the QHP due to a loss of Medicaid eligibility. The Final Rule also clarifies that unsolicited contacts by email and texting are “cold-call” activities and therefore prohibited.

Effective date: 60 days after publication.


Subpart F, part 438

CMS has aligned the appeal and grievance processes for Medicaid Managed Care Organizations (MCOs) with the processes that apply to Medicare Advantage plans and private coverage (individual and group). CMS was concerned that existing differences can cause inefficiencies for insurers and confusion for beneficiaries, especially those who are transitioning between sources of coverage. CMS also extended appeals and grievance procedures for Medicaid MCOs and Prepaid Inpatient Ambulatory Plans (PIHPs) to Prepaid Ambulatory Health Plans (PAHPs) that cover medical services, which were previously excluded from appeal and grievance requirements. In addition, CMS clarified in the Final Rule that all references to process time frames are in calendar days, consistent with appeals and grievance processes in the Medicare Advantage program.
Statutory basis and definitions ($438.400)

The Final Rule replaces the term “action” with the term “adverse benefit determination”, which includes denials, limitations, and similar determinations based on medical necessity, appropriateness, health care setting or effectiveness of a covered benefit, and disputes involving potential enrollee financial liability. This change conforms to the use of the term in the private sector to permit Medicaid plans to “consolidate processes across Medicaid and private health care coverage sectors.”

- Effective date: No later than the rating period for contracts starting on or after July 1, 2017.

General Requirements ($438.402)

Levels of Appeals. In the Final Rule, the Medicaid plan’s appeals process can have only one level of internal appeal. If the beneficiary receives a notice of adverse determination from the appeal, s/he can then request a state fair hearing (SFH).

Provider Appeals. The Final Rule clarifies that, if state law permits and with the written consent of the enrollee, a provider or an authorized representative may request an appeal, file a grievance or request a SFH on behalf of an enrollee.

Timeframe for Filing Appeals. CMS removed the option for states to select a timeframe between 20 and 90 days for an enrollee to file an appeal. The Final Rule adopts a timeframe of 60 calendar days for enrollees to file an appeal at the plan level following an adverse benefit determination, consistent with Medicare Advantage and private health coverage requirements.

- Effective date: No later than the rating period for contracts starting on or after July 1, 2017.

Timely and adequate notice of adverse benefits determination ($438.404)

The Final Rule clarifies that the notice of adverse benefit determination must explain the right of the enrollee 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, including medical necessity criteria and standards used to set coverage limits.

CMS sets minimum standards for the types of information that must be collected and contained in the record of each grievance and appeal. In addition, the notice must describe the enrollee’s and provider’s right to request an appeal of the Medicaid plan’s adverse benefit determination, and include information on exhausting the one level of managed care plan appeal and the enrollee’s right to request a SFH.

- Effective date: No later than the rating period for contracts starting on or after July 1, 2017.

---

1 In other words, the effective date of this provision is the beginning of the first 12-month period of a plan contract starting on or after July 1, 2017. For example, if a state structures its Medicaid plan contracts by calendar year, the effective date would be January 1, 2018. If a state structures its contracts on a state fiscal year that runs October to September, the effective date would be October 1, 2017.
Handling of grievances and appeals (§438.406)

The Final Rule provides that individuals who were involved or are subordinates of individuals involved in any previous level of review are excluded from making decisions on a grievance or appeal. In addition, individuals who make decisions on appeals and grievances must take into account all comments, documents, records, and other information submitted by the enrollee, regardless of whether the information was considered in the initial review.

Effective date: No later than the rating period for contracts starting on or after July 1, 2017

Resolution and Notification: Grievances and Appeals (§438.408 and §431.244(f))

Timeframe for deciding appeal. The Final Rule shortens the timeframe in which Medicaid plans must make a decision regarding an enrollee’s appeal from the current 45 days to 30 calendar days.

Timeframe for deciding expedited appeal. The Final Rule modifies the current timeframe for a decision on an expedited appeal from three working days from receipt of a request to 72 hours.

Effective date: No later than the rating period for contracts starting on or after July 1, 2017

Requests for SFH. The Final Rule requires enrollees to exhaust the Medicaid plan’s internal appeals process before requesting a SFH. Under current rules, states have the discretion to allow an enrollee to request a SFH while the plan’s appeal process is underway. In addition, the Final Rule provides that the enrollee is deemed to have exhausted a plan’s internal appeals process and may initiate a SFH if the plan fails to adhere to applicable notice and timing requirements.

The Final Rule also extends the timeframe for an enrollee to request a SFH from the current range of 20 – 90 days from date of notice of the plan’s adverse determination to 120 days in order to give enrollees more time to gather necessary information and seek assistance.

The Final Rule also provides that the state may offer and arrange for an external medical review at the enrollee’s option, but only if the review is independent of both the state and the plan, offered without cost to the enrollee, and does not extend any of the appeals timeframes or disrupt continuation of benefits.

The Final Rule also requires a Medicaid plan to implement 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.

Effective date: 60 days after publication.

Medical Loss Ratio (§438.4, §438.5, §438.8, and §438.74)

The Final Rule requires a minimum medical loss ratio (MLR) for MCOs, PIHPs and PAHPs be calculated, reported and used in the development of actuarially sound capitation rates.
The Final Rule establishes a minimum MLR threshold of 85 percent. Rates must be developed so that the plan would reasonably achieve a medical loss ratio standard of at least 85 percent for the rate year. States are permitted to require an MLR threshold greater than 85 percent provided the rates are adequate for reasonable, appropriate, and attainable non-benefit costs.

States are not required to collect remittances from Medicaid plans experiencing a MLR below the minimum percentage. However, if the state does collect remittances from a plan, it is to forward the federal share of any such remittance to CMS. CMS does not provide a methodology for determining remittances; the responsibility for developing a methodology lies with the state.

The calculation of the MLR is based on the same calculation used for QHPs with some differences in recognition of the unique nature of the Medicaid program. The numerator generally includes incurred claims, expenditures on activities that improve health care quality, and certain other definitions and limits. The Final Rule provides that expenditures related to fraud prevention activities will be incorporated into the Medicaid MLR in the event that such expenditures are included in the MLR for the private market at 45 CFR Part 158. The Final Rule also sets standards for determining whether an activity improves health care quality, is specific to an External Quality Review activity, or is related to Health Information Technology and meaningful use.

The Final Rule defines the denominator for the MLR to consist of a plan’s premium revenue (plus any additional payments such as “kick-payments”) less any expenditure for federal or state taxes and licensing or regulatory fees. Community Benefit Expenditures, which are defined as expenditures for activities or programs that seek to achieve the objectives of improving access to health services, enhancing public health and relief of government burden (45 CFR 158.162(c)), can be deducted up to prescribed limits (e.g., three percent of earned premiums or the highest premium tax rate in the state).

The Final Rule includes a “credibility adjustment” methodology that provides small plans with a special adjustment to their MLR in recognition that large unexpected claims can have a disproportionate impact on small plans.

States are to calculate, on an annual basis, their MLR on a contract-wide basis, however, CMS permits flexibility for states to choose to separate the MLR calculation by Medicaid eligibility group based on differences driven by the federal medical assistance percentage. If a state chooses to do so, the state may not apply different standards of review or MLR minimums to different eligibility groups. CMS also notes that states should consider the parameters of the minimum MLR when developing any risk sharing mechanisms to ensure upper and lower bounds are within those MLR standards.

The Final Rule requires plans to submit a report to the state meeting specific content standards and in the time and manner established by the state within 12 months of the end of the MLR reporting year. Plans that enter a new market do not need to calculate or report their MLR in the first year they contract with the state if the state chooses to exclude that MCO from the MLR calculation that year. In any case where a state makes a retroactive adjustment to the rates that
affect a MLR calculation for a reporting year, the plan would need to recalculate the MLR and provide a new report with the updated figures.

States are to report to CMS a summary description of the outcomes of the MLR calculations for each reporting year and as noted above re-pay the federal share of any remittances the state chooses to collect from the Plans. If a state does not segregate MLR reporting by population, the state will need to submit its methodology for determining the federal share of the remittance.

Effective date: MLR calculation and reporting applies no later than the rating period for contracts starting on or after July 1, 2017. Capitation rates must be set so that the managed care plan is projected to meet at least an 85 percent MLR no later than the rating period for Medicaid managed care contracts starting on or after July 1, 2019.

Standard Contract Provisions (§438.3, §438.6)

The Final Rule implements a variety of new requirements for contract terms and actuarial soundness for rate setting development, including the following:

- States are required to submit Medicaid plan contracts to CMS for review/approval. In the preamble, CMS notes that timeframes and detailed processes for federal review/approval will be set forth in future subregulatory guidance. For states seeking approval of contracts prior to a specific effective date, proposed final contracts must be submitted to CMS for review no later than 90 days before the effective date of the contract. CMS did not establish regulatory timeframes for CMS to finalize a contract.
- The Final Rule adds criteria for services that may be provided by a plan in lieu of services that are explicitly part of the state plan.
- All plan contracts must mandate provider identification of provider-preventable conditions as a condition of payment and must provide the state and federal entities the right to inspect and audit any records or documents at any time.
- Plans must submit audited financial reports annually (effective for contracts starting on or after July 1, 2017).
- The Final Rule confirms that plans providing prescription drug coverage must comply with statutory requirements applied to Medicaid fee-for-service (FFS) programs. That is, plans may operate formularies but must guarantee off-formulary coverage for medically necessary prescription drugs marketed by pharmaceutical companies participating in the Medicaid Drug Rebate program. Similarly, prior authorization processes must meet statutory requirements to respond within 24 hours of a request for prior authorization and dispense at least a 72-hour supply of a covered outpatient prescription drug in an emergency situation.
- The Final Rule requires plans to report drug utilization data necessary for the state to bill manufacturers for rebates within 45 calendar days after the end of each quarterly rebate period. Such utilization information is to include the total number of units of each dosage form and strength and package size by NDC for each covered outpatient (OP) drug. For this report, plans must have procedures in place to exclude such data for drugs subject to 340B Drug Pricing Program discounts. (Effective for contracts starting on or after July 1, 2017.)
• Plans that provide coverage of OP drugs are required to operate a drug utilization review (DUR) program that is consistent with the federal standards that states must meet. That is, the DUR program must assure that prescriptions are: appropriate; medically necessary; and not likely to result in adverse medical results. The plan is required to provide a detailed description of its DUR program activities to the state on an annual basis. (Effective for contracts starting on or after July 1, 2017.)

• In addition, plans must provide a response to a request for prior authorization for a covered OP drug by telephone or other telecommunication device within 24 hours of the request and dispense a 72 hour supply of a covered OP drug in an emergency situation. Note that in a lengthy preamble discussion of the prescription drug rules, CMS specifies that plans are permitted to have different formularies and prior authorization programs. However, CMS also states that if a plan’s formulary or utilization management tools do not provide access to a medically necessary covered outpatient drug that is otherwise covered by the state plan for individuals in FFS, the plan and state must ensure access to the drug consistent with the prior authorization requirements that states must meet. CMS further specifies that prior authorization requirements cannot result in patients being unable to access covered outpatient drugs of manufacturers participating in the drug rebate program when such drugs are medically necessary.

• In states that delegate responsibility for coordination of benefits for dual eligible beneficiaries to a Medicaid plan and use the automated crossover process under which claims first submitted to the Medicare fee-for-service program are then submitted to the state when Medicaid payment is due, the plan contract would need to provide that the plan sign a Coordination of Benefits Agreement and participate in the automated crossover process administered by Medicare. (Effective for contracts starting on or after July 1, 2017.)

• The Final Rule adds a new section that permits Medicaid plans to receive a capitation payment from the state for an enrollee aged 21 to 64 who spends a portion of the month for which the capitation is made as a patient in an institution for mental disease (IMD) so long as the facility is a hospital or sub-acute facility providing psychiatric or substance use disorder services and the stay in the IMD is less than 15 days that month. The contract may not explicitly require the plan to use IMD facilities but could include in its list of Medicaid-covered services to be provided under the contract.

• CMS establishes minimum recordkeeping requirements for Medicaid plans and subcontractors of at least 10 years for enrollee grievance and appeal records; MLR reports; and certain other data, documentation and information specified in other regulatory sections such as encounter data, data used for actuarial soundness certifications, etc. (Effective for contracts starting on or after July 1, 2017.)

Effective date: 60 days after publication unless otherwise indicated.

Setting Actuarially Sound Capitation Rates for Medicaid Managed Care Programs (§438.2, §438.4, §438.5, §438.6, and §438.7)

The Final Rule establishes a variety of new requirements relating to the rate-setting process.
Actuarially sound capitation rates

The Final Rule defines actuarially sound capitation rates (§438.4) as rates that are projected to provide for “all reasonable, appropriate, and attainable costs that are required under the terms of the contract” for the time period and covered populations. To be approved by CMS as actuarially sound any proposed differences among capitation rates according to covered populations must be based on valid rate development standards and not based on the federal match rate associated with a particular population (effective 60 days after publication). Capitation rates must be adequate to ensure availability and timely access to services, adequate networks, and coordination and continuity of care (effective no later than rating period for contracts starting on or after July 1, 2018). Finally, capitation rates must be developed in a way that a Medicaid plan would reasonably achieve a MLR of at least 85 percent for the rate year (effective no later than rating period for contracts starting on or after July 1, 2019).

- Effective date: see above.

Use of rate cells

The Final Rule requires the use of “rate cells”, under which enrollees are grouped together based on the similarity of their characteristics and expected health care costs. Capitation rates must be specific to the payment attributable to each rate cell under the contract (effective no later than rating period for contracts starting on or after July 1, 2018). The rates must appropriately account for the expected benefit costs for enrollees in each rate cell and for a reasonable amount of the non-benefit costs of the plan (effective no later than rating period for contracts starting on or after July 1, 2017). Each individual rate paid to each MCO must be certified as actuarially sound with enough detail to understand the specific data, assumptions, and methodologies behind that rate. The Final Rule allows states to increase or decrease the capitation rate certified per rate cell by 1.5 percent, which results in a three percent range, without submitting a revised rate certification for CMS review and approval (effective no later than rating period for contracts starting on or after July 1, 2018). CMS developed this rule based on its determination that fluctuation of plus or minus 1.5 percent does not change the actuarial soundness of a capitation rate.

- Effective date: see above.

Rate development process

For the rate development standards (§438.5), the Final Rule sets forth standards and steps the state actuary has to follow when establishing Medicaid managed care capitation rates. The six steps include:

- Collect or develop appropriate base utilization and price data from historical experience;
- Develop and apply trends to project benefit costs in the rating period, including trends in utilization and prices of benefits;
- Make appropriate and reasonable adjustments to account for changes to the base data, programmatic changes, non-benefit components, and any other adjustments necessary to establish actuarially sound rates;
- Develop projected costs for non-benefit costs in the rating period as part of the capitation rate;
- Consider historical and projected MLR of the Medicaid plan; and
- For programs that use a risk adjustment process, select an appropriate risk adjustment methodology, apply it in a budget neutral manner, and calculate adjustments to plan payments as necessary (effective 60 days after publication).

States and their actuaries must use the most appropriate data, with the basis of the data being no older than from the three most recent and complete years prior to the rating period under development. There may be reasons why older data are necessary and CMS permits a state to request an exception to the requirement, provided the state submits a description of why an exception is needed and a corrective action plan that details how the problems will be resolved in no more than two years. In addition, in the preamble to the Final Rule CMS indicates that states can supplement the audited financial reports with more recent data in unaudited financial reports if such information is useful in the rate setting process.

The Final Rule creates a general standard that trend factors be reasonable and developed in accordance with generally accepted actuarial principles and practices, and that they be developed primarily from actual experience of the Medicaid population or from a similar population. CMS establishes standards for developing the non-benefit component of the rate which includes expenses related to administration, taxes, licensing and regulatory fees, reserve contributions, risk margin, cost of capital, and other operational costs.

- **Effective date:** no later than the rating period for contracts starting on or after July 1, 2017, unless otherwise indicated.

### Risk sharing and incentive arrangements

The Final Rule addresses several “Special Contract Provisions Related to Payment” in new §438.6. For example, the rule includes changes to previous standards for incentive arrangements. Such arrangements must be designed to support program initiatives tied to meaningful quality goals and performance measure outcomes. For withhold arrangements (i.e., the state retains a portion of the base capitation rate subject to performance of specified measures or outcomes related to the contract), CMS requires that the capitation rate minus any portion of the withhold amount that is not reasonably achievable must be certified as actuarially sound.

- **Effective date:** for provisions related to incentive arrangements, 60 days after publication; for provisions addressing withhold arrangements, effective no later than the rating period for contracts starting on or after July 1, 2017.

### Provider payment arrangements

The Final Rule provides that a state may not direct an MCO’s expenditures under the contract. A state may require the MCO to: implement value-based purchasing models for provider reimbursement (e.g., pay for performance arrangements, bundled payments); participate in a multi-payer delivery system reform or performance improvement initiative; participate in a
Medicaid-specific delivery system reform (e.g., patient-centered medical homes, efforts to reduce low birth weight babies); adopt a minimum or maximum fee schedule for network providers that provide a particular service; or provide a uniform increase for providers that provide a particular service under the contract.

- Effective date: no later than the rating period for contracts starting on or after July 1, 2017

Pass-Through Payments Under Plan Contracts.

In the preamble to the Final Rule, CMS notes that some states mandate pass-through supplemental payments for hospital, physician and nursing facilities under plan contracts. CMS asserts such arrangements are not in compliance with existing federal regulations that prohibit such payments through plans. However, CMS acknowledges that in several states safety net providers rely on these supplemental payments. The Final Rule specifies that states may require MCOs to make pass-through payments to network providers that are hospitals, physicians, and nursing facilities. However, these payments to hospitals will be phased out over a 10 year period and similar payments for physicians and nursing facilities will end in five years (no phase-out is required).

- Effective date: no later than the rating period for contracts starting on or after July 1, 2017

Rate certification submission

The Final Rule (§438.7) requires states to receive CMS approval of the rate certification in addition to contract approval. The rate certification is to describe and provide the necessary documentation and evidence that the rates were developed consistent with generally accepted actuarial principles and practices and regulatory standards. Key elements include:

- **Timing.** States must submit to CMS for review and approval, all MCO, PIHP, and PAHP rate certifications concurrent with the review and approval process for contracts (effective 60 days after publication).

- **Trend Factors and Non-Benefit Components.** The rate certification must be detailed enough so that CMS or an actuary can understand and evaluate the development and reasonableness of the trend and any meaningful differences among trend factors. The rate certification must also provide enough detail on the non-benefit component of the rate so that CMS or an actuary can understand each type of non-benefit expense and evaluate the reasonableness of each cost assumption.

- **Adjustments to capitation rates.** All material adjustments, which are determined by the actuary, used to develop the rates must be adequately described in the rate certification with enough detail so that CMS or an actuary can understand and evaluate: how each material adjustment was developed and its reasonableness for the enrolled population; the cost impact of each material adjustment; and the aggregate cost impact of non-benefit material adjustments. As CMS gains experience in reviewing adjustments and further consults with states, CMS may issue guidance on what it believes to be material and non-
material adjustments. Until such guidance is issued, CMS expects the actuary to exercise good judgment.

- **Risk adjustment.** The Final Rule establishes standards in the certification for prospective and retrospective risk adjustment. The prospective risk adjustment methodologies should be of sufficient detail for CMS to understand and evaluate the model selected and data used by the state; the method for calculation of the relative risk factors and the reasonableness and appropriateness of the method in measuring the risk of the respective populations; the magnitude of the adjustment on the capitation rate; and an assessment of the predictive value of the methodology. Retrospective risk adjustments must meet similar standards.

- **Retroactive capitation adjustments.** A retroactive adjustment must be submitted to CMS and be supported by a rationale for the adjustment, and the data, assumptions and methodologies must be adequately described in detail. The adjustment must be certified by an actuary. However, as noted above, the state may increase or decrease the capitation rate per rate cell up to 1.5 percent without submitting a revised rate certification.

- **Effective date:** no later than the rating period for contracts starting on or after July 1, 2017, unless otherwise indicated.

Other Payment and Accountability Improvements (§438.230)

CMS clarifies current regulations regarding an MCO’s delegation of contractual responsibilities to other entities through subcontracts. The Final Rule more clearly states that regardless of any relationship that a MCO may have, it alone is accountable for complying with all terms of the contract with the state.

- **Effective date:** no later than the rating period for contracts starting on or after July 1, 2017

Program Integrity (§438.600, §438.602, §438.604, §438.606, §438.608, and §438.610)

The Final Rule consolidates all state responsibilities associated with program integrity into one section.

**State responsibilities** (§438.602)

- **Screening and enrollment** (§438.602(b)). The Final Rule requires states to screen and enroll (i.e., execute agreements with) all Medicaid health plan network providers that are not otherwise enrolled with the state to provide services to FFS Medicaid beneficiaries. Such screening and enrollment does not oblige network providers to also render services to FFS beneficiaries. Further, plans may make the state’s enrollment form available to providers to speed network contracting, and may conduct their own additional level of provider screening if desired. States may incorporate other screening requirements into their contracts. Plans may contract with providers for up to 120 days
pending outcome of the state screening but must terminate the contract if the state has not enrolled the provider by the end of the 120-day period.

- **Effective date §438.602(b):** no later than the rating period for contracts starting on or after July 1, 2018

  - **Ownership and control disclosures.** The state must review the ownership and control disclosures submitted by a Medicaid plan and any subcontractors, and conduct federal database checks to determine whether the entity, any person with an ownership or control interest, or any agent or managing employee, is debarred, suspended or otherwise excluded from participating in federal procurement activities. The state must conduct federal database checks at the time of entering into the contract and no less frequently than monthly thereafter; and promptly notify the plan if the state determines a match.

- **Effective date: No later than the rating period for contracts starting on or after July 1, 2017**

**Data submissions (§438.604)**

The Final Rule specifies data, information and documentation that must be submitted by each Medicaid plan to the state, including encounter data and other data generated by the health plan for purposes of rate-setting; data by which the state may determine that the entity met the MLR standards; data to ensure solvency standards are met; data to ensure availability and accessibility of services; data relating to ownership or criminal offenses against federal health programs; an annual report on recoveries of overpayments; and any other data related to the performance of the entity’s obligations as specified by the Secretary. For example, the Secretary could require plans to submit to the state data elements from network provider claims, such as the NPI, services dates, place of service, and procedure codes to enable the state to review the claims paid for program integrity purposes.

- **Effective date: No later than the rating period for contracts starting on or after July 1, 2017**

**Plan certification (§438.606)**

The Medicaid plan must certify the data (including network adequacy) submitted to the state. The Final Rule clarifies that, while the plan’s CEO or CFO is personally responsible for the accuracy, completeness, and truthfulness of the reported data, documentation, and information, the CEO or CFO may delegate authority to a direct report to sign on the CEO’s or CFO’s behalf. CMS notes in the preamble to the Final Rule that it expects the certification to be based on a “reasonably diligent” review of the data, documentation, and information underlying the certification; however, the Final Rule itself does not specify this review requirement. In addition, the Final Rule retains language from the existing rule allowing the certification to be based on the CEO or CFO’s “best information, knowledge, and belief”; the proposed rule would have deleted this language. Further, the state must periodically, but no less frequently than once every three years, conduct an independent audit of the accuracy, truthfulness, and completeness of the encounter and financial data submitted by each plan.
CMS expanded the elements that must be included in a Medicaid plan’s program integrity/compliance program and administrative procedures to detect and prevent fraud, waste and abuse (FWA), and extended those elements to subcontractors, to the extent that the subcontractor is delegated responsibility by the plan for coverage of services and payment of claims under the contract between the state and plan. As part of a plan’s FWA program, the state must require the plan to suspend payment to a network provider when there is a credible allegation of fraud unless the state determines there is good cause not to do so. In addition, plans must establish procedures and a system, including dedicated staff, for routine internal monitoring and auditing of compliance risks, prompt response to compliance issues, and correction of problems to reduce the potential for recurrence.

The Final Rule imposes additional requirements for performance to be included in a Medicaid plan contract, including reporting to the state within 60 calendar days of identification when the plan identifies receipt of payments in excess of the capitation rate or other payments made in error, (e.g. kick-payments or withhold arrangements). The plan contract must address retention policies for recoveries of overpayments made by the plan to providers that were excluded from Medicaid participation, or that were due to fraud, waste or abuse, including reporting timelines, documentation, and whether recoveries remain with the plan or are forwarded to the state. States are to take such recoveries into account in the development of future actuarially sound capitation rates. The plan must have a mechanism in place for network providers to report the receipt of overpayments and to return such overpayments to the plan within 60 days.

This section primarily consists of non-substantive technical corrections such as making terminology consistent with other regulations. However, the Final Rule clarifies that the intermediate sanctions in §438.700(c) (e.g., appointment of temporary management, suspension of new enrollment, granting enrollees the right to terminate enrollment without cause) “may” be used by the state rather than “must” be used by the state. Also, the Final Rule deletes PIHPs and PAHPs from the state’s determination that unapproved or misleading marketing materials have been distributed, as the underlying provision only applies to a “managed care entity”.

The Final Rule requires that all beneficiaries must be given the information, education, and opportunity to participate actively in their choice of managed care plan, and states must develop informational notices to clearly explain the implications of not actively making a plan selection.
Notices must include specified elements, such as description of any lock-in, disenrollment opportunities and rights, and contact information for the beneficiary support system (see below).

If a state uses a passive enrollment process, a beneficiary who does not make a selection can be assigned to a qualified Medicaid plan that has adequate capacity for new enrollment and is not subject to an enrollment sanction. In doing so, the state must take into consideration existing provider-individual relationships and if that is not possible, equitably distribute enrollees among the participating plans. However, the state has the flexibility to consider additional factors when assigning beneficiaries such as geographic location of the individual, previous plan assignments, quality assurance and improvement performance, and other reasonable criteria.

- Effective date: 60 days after publication

**Disenrollment Standards and Limitations (§438.56)**

CMS added a new cause for disenrollment for beneficiaries enrolled in a managed long term services and supports program (MLTSS). If a state does not permit participants to switch MLTSS plans at any time, the state must permit an enrollee to disenroll from their MLTSS plan when the termination of a provider from the plan’s MLTSS network would result in a disruption in the enrollee’s residence or employment.

- Effective date: 60 days after publication

**Beneficiary Support System (§438.71)**

The Final Rule requires states to develop and implement a beneficiary support system to provide support before and after managed care enrollment. The system must include

- Outreach to beneficiaries and authorized representatives
- Choice counseling for all beneficiaries
- Assistance for enrollees in understanding managed care, and
- Assistance for enrollees who use, or express a desire to receive long term services and supports (LTSS).

The beneficiary support system must be available to beneficiaries in multiple ways including phone, internet, in-person, and via auxiliary aids and services when requested.

States must provide choice counseling services for any potential enrollee or to managed care enrollees when they have an opportunity to change enrollment. The Final Rule defines choice counseling to mean the provision of information and services designed to assist beneficiaries in making enrollment decisions, including answering questions and identifying factors to consider when selecting a Medicaid plan and primary care providers. States have the flexibility to decide who can provide choice counseling and to use multiple entities for different functions of the beneficiary support system.

Choice counselors are considered “enrollment brokers” and accordingly must meet independence and conflict of interest standards with respect to relationships with Medicaid plans and providers.
Entities that provide legal representation generally cannot also serve as choice counselors unless organizational firewalls are put in place.

In providing assistance for enrollees who use or express a desire to receive LTSS, the state’s beneficiary support system must provide:

- An access point for complaints and concerns about plan enrollment, access covered services, and other related matters
- Education on enrollees’ grievance and appeal rights with the plan; the SFH process; enrollee rights and responsibilities; and additional resources outside of the plan
- Assistance in navigating the plan grievance and appeal process as well as appealing adverse benefit determinations by the plan, and
- Review and oversight of LTSS program data to assist the state on identification and resolution of systemic issues.

Effective date: No later than the rating period for contracts starting on or after July 1, 2018

Coverage and Authorization of Services and Continuation of Benefits While the MCO, PIHP, or PAHP Appeal and the SFH are Pending (§438.210 and §438.420)

Utilization controls. CMS believes that it is important that authorization periods for enrollees with ongoing and chronic care needs, including LTSS, avoid disruptions in care. The Final Rule requires state contracts to ensure that service authorization standards do not disadvantage individuals who have ongoing chronic conditions or LTSS needs. In addition, utilization controls may not interfere with the enrollee’s freedom to choose a method of family planning.

Medical necessity. CMS revised the criteria for defining medically necessary services to include early and periodic screening and diagnosis of beneficiaries under age 21 (EPSDT); and replaced the term “health impairments” with “an enrollee’s disease, condition, or disorder that results in health impairment and/or disability”. The Final Rule also requires the state contract with Medicaid plans to specify what constitutes “medically necessary services” in a manner that is no more restrictive than that used in the state Medicaid program, including quantitative and non-quantitative treatment limits. The Final Rule directs plans to authorize LTSS based on an enrollee’s current needs assessment and consistent with the person-centered service plan.

Coverage pending appeal. CMS removed the existing regulatory provision that permits plans to discontinue coverage of services pending appeal when the time period or service limits of a previously authorized service have been met. Accordingly, an enrollee must continue to receive benefits without interruption through the conclusion of the SFH process if the enrollee appeals an adverse benefit determination.

To continue benefits at the end of an authorization period, enrollees must request continuation by the later of: (1) ten calendar days from the date the plan sends the notice of adverse benefit determination; or (2) the intended effective date of the plan’s adverse benefit determination.

Therefore, if the plan does not send the notice of the adverse benefit determination at least ten calendar days before the termination or reduction of previously authorized services, the enrollee
will have longer than the original authorization period to timely file a request for continuation of benefits.

If the adverse benefit determination is ultimately upheld, the plan may institute recovery procedures against the enrollee to recoup the cost of any services required to be continued while the appeal was pending but only if permitted in the contract with the state. While the decision to hold the beneficiary financially liable for such services is left to the state, such practices should be consistent across both FFS and MCO delivery systems within the state.

- Effective date: No later than the rating period for contracts starting on or after July 1, 2017

Continued Services to Beneficiaries (§438.62)

The Final Rule requires states to have a transition of care policy in place for individuals moving to managed care from FFS, or from one Medicaid plan to another when, without continued services, an enrollee would experience serious detriment to their health or be placed at risk of hospitalization or institutionalization (§438.62). Elements of transition policies must include:

- Permitting the enrollee to continue to receiving services from their current provider “for a period of time”
- Referring the enrollee to an appropriate network provider
- Assuring the state or plan complies with requests from the beneficiary’s new health plan for historical utilization data in compliance with federal and state law
- Assuring that the enrollee’s new provider is able to obtain appropriate medical records.

Additional procedures may be specified by the Secretary. The rule gives states the flexibility to develop transition policies to apply to all Medicaid plans or permit plans to establish different policies as long as the state’s minimum standards are met.

- Effective date: No later than the rating period for contracts starting on or after July 1, 2017

Applicability of Care Coordination (§438.208(a))

The Final Rule sets general requirements for care coordination by Medicaid plans with two exceptions. 1) The state may exempt a PIHP or PAHP from care coordination requirements based on the scope of the entity's services and the way the state has organized the delivery of managed care services. 2) The state may determine the extent to which plans that serve dually eligible enrollees who are also enrolled in a Medicare Advantage plan must meet care coordination requirements such as those described in §438.208(b) Care Coordination Activities (see next section).

- Effective date: No later than the rating period for contracts starting on or after July 1, 2017

Care Coordination Activities (§438.208(b))

The Final Rule expands care coordination requirements for Medicaid plans to involve coordination between settings of care, including appropriate hospital discharge planning and
services provided outside of the Medicaid plan, including other plans and FFS Medicaid, as well as services of community and social support providers. Plans must make best efforts to complete initial health risk screenings within 90 days of the effective date of enrollment for all new enrollees; and should maintain and share an enrollee health record with an enrollee’s providers and suppliers. In addition, plans must provide enrollees with information on how to contact their care coordinator. The Final Rule also requires care coordination to include specialists and other types of providers and not solely primary care providers.

- Effective date: No later than the rating period for contracts starting on or after July 1, 2017

**Long-Term Services and Supports (§438.208(c))**

States are required to have mechanisms in place to identify people with special health care needs and communicate that information to Medicaid plans. The Final Rule adds enrollees who need LTSS to the group of people with special care health needs. States may use their staff, enrollment brokers and the Medicaid plans as part of their identification mechanisms.

Assessments of individuals needing LTSS are to be conducted by appropriate individuals who meet the state’s requirements for LTSS service coordination. CMS clarifies that assessments for LTSS are in addition to health risk screenings (HRS) performed by plans within the first 90 days of enrollment. HRSs lack the level of detail of a comprehensive assessment and would be inappropriate as the sole source of information for the development of a treatment/service plan.

Treatment or service plans are required for enrollees using LTSS, must conform to person-centered standards consistent with the home and community-based services (HCBS) final rule and be developed by the enrollee’s provider or an individual meeting the plan’s or state’s service coordination provider standards in consultation with health care professionals and providers serving the enrollee. CMS states this change is to permit a MCO to use internal staff for service coordination.

- Effective date: No later than the rating period for contracts starting on or after July 1, 2017

**Managed Long-Term Services and Supports (§438.2, §438.3, §438.70, §438.71, §438.214, §438.816)**

The Final Rule formally codifies the ten elements inherent in a strong MLTSS program that were introduced in CMS’s MLTSS guidance in 2013. The regulatory revisions ensure that all MLTSS programs operate in accordance with these elements:

- Adequate Planning
- Stakeholder Engagement
- Provision of Home and Community Based Services (consistent with the Americans with Disability Act, the *Olmstead v. L.C.* decision, etc.)
- Support for Beneficiaries
- Person Centered Process
- Comprehensive, Integrated Service Package
- Qualified Providers
Participation Protections
Quality

For purposes of these MLTSS provisions, the Final Rule defines LTSS as services and supports that 1) are provided to beneficiaries of all ages who have functional limitations and/or chronic illnesses; and 2) 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, a worksite, a provider-owned or controlled residential setting, a nursing facility, or other institutional setting. The intent of the definition is to reflect that community-based services are largely non-medical in nature and focused on functionally supporting people living in the community.

In addition, to encourage stakeholder involvement, the Final Rule requires that states create a stakeholder group consisting of LTSS beneficiaries, providers and others to ensure their opinions are solicited and addressed during the design, implementation and oversight of the MLTSS program. Also, each Medicaid plan, when providing LTSS benefits, must establish and maintain a member advisory committee that is to include at least a reasonably representative sample of the LTSS population. Both state stakeholder groups and plan advisory committees should include enrollees, enrollee representatives and family members.

Effective date: No later than the rating period for contracts starting on or after July 1, 2017 (most provisions)

Availability of Services, Assurances of Adequate Capacity and Services, and Network Adequacy Standards (§438.206, §438.207, §438.68, §440.262)

CMS stipulates that the state must establish, at a minimum, network adequacy standards including time and distance standards for the following provider types (§438.68):
- Primary care (adult and pediatric)
- OB/GYN
- Behavioral health (adult and pediatric; both mental health and substance use disorder)
- Specialist (adult and pediatric)
- Hospital
- Pharmacy
- Pediatric dental
- LTSS
- Additional provider types when it promotes the objectives of the Medicaid program

CMS defers to states in establishing the specific time and distance standards. They may vary by provider type and/or by geography (e.g. urban vs. rural). In setting timely access standards, services may be reasonably classified as routine, urgent or emergency care. States may impose additional kinds of network standards. States are required to publish the network adequacy standards on their Medicaid managed care websites.

States must include a contract provision in all Medicaid plan contracts requiring plans to demonstrate sufficient and timely access to network family planning providers, and to permit enrollees to access family planning services out of network without a referral.
Similar to the approach used for health care providers, states must develop time and distance network adequacy standards for MLTSS providers when enrollees travel to those providers to receive service. States are required to develop network adequacy standards other than time and distance standards (e.g., enrollee-to-provider ratios) for MLTSS providers that travel to enrollees.

These standards are applicable only to the services covered under the Medicaid plan contract. States are permitted to vary the standards in different geographic areas to account for the number of providers practicing in a particular area. In developing the standards, states must also consider the ability of providers to ensure physical access, accommodations, and accessible equipment available for Medicaid enrollees with physical or mental disabilities, and the ability of network providers to communicate with limited English proficient enrollees in their preferred language.

The Final Rule provides for exceptions to the standards in recognition of special situations. Such exceptions must be specified in the contract and be based at a minimum on the number of health care professionals in a given specialty practicing in the service area. States must monitor enrollee access in such exceptions and report findings to CMS in their annual managed care monitoring report.

CMS notes that states need to have mechanisms (e.g., enrollee surveys, reviewing encounter data, reporting HEDIS measures, secret shopper efforts, evaluations of consumer service calls) in place for ensuring that plan networks meet network adequacy standards. However, CMS does not require that specific methods or approaches be used.

Further, in addition to the current regulatory requirement that Medicaid plans submit documentation to the state regarding network adequacy at the time the plan enters into a contract and when there is a significant change in operations, the Final Rule requires plans to submit such documentation and the state to certify network adequacy on at least an annual basis.

- Effective date: No later than the rating period for contracts starting on or after July 1, 2018 (most provisions)

Quality of Care (Subparts D and E of Part 438)

Current regulations require that states contracting with Medicaid plans draft and implement a quality strategy and that plans be reviewed annually by External Quality Review Organizations (EQROs). In the Final Rule, CMS states that it is implementing changes to strengthen quality measurement and improvement efforts in Medicaid managed care based on three principles:

- Transparency (e.g., public reporting of quality of care information)
- Alignment with other systems of care (e.g., drawing from Medicare Advantage and Marketplace quality standards), and
- Consumer and stakeholder engagement (e.g., strengthen consumer role in health care decision-making).
The Final Rule makes changes to the definitions of EQROs and their reviews, including adding a review of the new state-developed network adequacy standards to the EQRO scope of work (see below). CMS also announces it may identify national Quality Assurance and Performance Improvement (QAPI) performance measures and topics for Performance Improvement Projects (PIPs) that must be included alongside any state-specified measures and topics in state contracts with their Medicaid plans. These new federal performance measures and PIPs will be developed through a public notice and comment process in the Federal Register. An exemption of a specific measure or PIP is allowed when appropriate (e.g., a measure may not be applicable for a state that does not enroll the relevant target population in managed care).

In addition to the other performance measures, when the state includes LTSS as covered services in plan contracts, plans must measure LTSS-specific performance, examining beneficiaries’ quality of life and plans’ rebalancing and community integration outcomes. Given the unique services and supports provided under MLTSS, plans must have specialized mechanisms to assess the quality and appropriateness of care furnished to enrollees receiving MLTSS.

Medicaid plans are to assess the services that an individual receiving LTSS has obtained with those that were in the individual’s LTSS treatment plan. Plans are also to participate in efforts by the state to prevent, detect, and remediate critical incidents based on state HCBS waiver program standards (i.e., incidents that adversely impact enrollee health and welfare and the achievement of quality outcomes described in the person centered plan). While CMS declines to specify a standard LTSS measure set or beneficiary survey at this time, it encourages states to consider including in their plan contracts language that incorporates the use of surveys to assess the experience of beneficiaries receiving LTSS.

- Effective date: 60 days after publication

State Review and Approval of MCOs, PIHPs, and PAHPs (new §438.332)

In the Final Rule, CMS determined not to proceed with a proposal requiring that MCOs undergo an accreditation review. Instead, states are to confirm the accreditation status of each plan at the time of contracting and annually thereafter, and publicly post the status of each plan on the state’s Medicaid website, including the name of the accrediting entity as well as the accreditation program and level for each plan, or that the plan has not been accredited.

- Effective date: No later than the rating period for contracts starting on or after July 1, 2017

Medicaid managed care quality rating system (§438.334)

CMS describes its plans to develop a Medicaid managed care quality rating system (MMC QRS) for all states contracting with Medicaid plans. The components of the rating system will be aligned with the same three summary indicators that are currently used to frame quality assessment programs for Marketplace QHPs: clinical quality; management, member experience; and plan efficiency, affordability, and management. CMS will develop, through a public notice and comment process, a standardized set of measures. CMS anticipates that proposed measures would be based on considerations such as importance of underlying performance, performance
gaps, reliability and validity, feasibility, and alignment. States are to prominently display the results of their quality rating systems online.

CMS will develop a methodology to determine the quality ratings for each plan, and states would be allowed to use state-identified measures in determining the rating for plans. The measure selection and methodology development process would occur every two to three years. A state could use a CMS-approved alternative or preexisting quality rating system in place of the federal system if ratings from the alternative system provide substantially comparable information.

CMS will utilize a public engagement process to develop the MMC QRS. This will include a series of listening session or town halls, requests for information and a series of notice and comment periods. CMS plans to issue MMC QRS guidance in 2018 and states would implement a MMC QRS by 2021.

- Effective date: no later than three years from the date of final notice published in the Federal Register

Activities related to external quality review (§438.358)

The Final Rule adds a new mandatory EQRO-related activity to evaluate and validate MCO network adequacy directly on an annual basis. These evaluations include assessments of how effectively a plan is meeting access standards, determining the accuracy of network information maintained by the plans, and telephone calls to providers that either assess compliance with a standard (e.g., wait times for an appointment) or the accuracy of provider information (e.g., participation in the plan). CMS will provide details of the network adequacy validation methodology in a forthcoming EQR protocol and there will be an opportunity for public feedback during development.

- Effective date: no later than July 1, 2018

Non-duplication of mandatory activities (§438.360)

To prevent duplication of effort in performing three existing mandatory EQRO-related activities, CMS permits states the option to rely on information obtained from a review performed by Medicare or a private accrediting entity such as NCQA. Standards of the Medicare or accreditation review must be comparable to those enumerated in the EQR protocols, and information generated by the accreditation review must be comparable to the information generated by an EQR-related activity. In addition, the state must provide information developed through this option to the EQRO. This option extends to: the validation of PIPs; the validation of performance measures; and the compliance review. The option does not extend to the network adequacy requirements because the scope of that activity will be determined through the EQRO protocol process.

- Effective date: no later than July 1, 2018
External quality review results (§438.364)

The rule adds several elements to those required in a state’s EQRO technical report, which must be made available to the public no later than April 30th of each year for the prior year. States may no longer unilaterally decide the appropriate methodology for comparative information about managed care plans or the flexibility to substantively revise the content of the final report except with evidence of error or omission, or upon requesting an exception from CMS.

- Effective date: no later than July 1, 2018

Federal financial participation (§438.370)

The Final Rule provides that managed care activities conducted on an MCO by an EQRO are eligible for an enhanced 75 percent federal match rate. EQR-related activities conducted on entities other than MCOs, or by an entity that is not an EQRO, would be eligible for the 50 percent administrative match rate.

- Effective immediately

State Monitoring Standards (§438.66)

Monitoring

The Final Rule requires the state to have a monitoring system for all of its managed care programs that address at a minimum:

- Administration and management
- Appeal and grievance systems
- Claims management
- Enrollee materials and customer services
- Finance, including medical loss ratio reporting
- Information systems, including encounter data reporting
- Marketing
- Medical management, including utilization management and case management
- Program integrity
- Provider network management
- Availability and accessibility of services
- Quality improvement
- Areas related to the delivery of LTSS
- All other provisions of the contract, as appropriate

State must use data collected from their monitoring activities to improve the performance of the managed care program. The Final Rule includes a list of minimum data elements that should be used for these purposes, such as enrollment and disenrollment trends for each Medicaid plan, member grievance and appeal logs, provider complaints, EQRO findings, and survey results.
Readiness Reviews

The Final Rule adopts a new standard for states to conduct readiness reviews of Medicaid plans prior to the effective date of new or modified managed care programs. Readiness reviews would consist of a desk review of documents and at the state’s option on-site interviews with plan staff and managerial leadership. CMS requires these reviews when prior to the state implementing a managed care program, when a specific plan has not previously contracted with the state, or when any plan will provide for the provision of covered benefits to new eligibility groups. The results must be submitted to CMS to inform its approval process for the related contract or contract amendment.

A state’s readiness review must assess the ability and capacity of the plan to perform satisfactorily in the following areas:
- Administrative staffing and resources
- Delegation and oversight of MCO entity responsibilities
- Enrollee and provider communications
- Grievance and appeals
- Member services and outreach
- Provider network management
- Program integrity/compliance
- Case management/care coordination/service planning
- Quality improvement
- Utilization review
- Financial reporting and monitoring
- Financial solvency
- Claims management
- Encounter data and enrollment information management

Program assessments

States must provide an annual managed care program assessment report to CMS no later than 180 days after each contract year. The report is to include information about and assessments of a variety of specified areas, including MCO financial performance, MCO encounter data reporting, and evaluation of quality performance.

- Effective date: no later than the rating period for contracts starting on or after July 1, 2017 (most provisions)

Information Standards (§438.10)

The Final Rule imposes state and managed care plan standards for beneficiary information that draws heavily from prior regulatory requirements but includes new elements that permit both states and managed care plans to make beneficiary information available in electronic form provided they meet certain standards.
Basic rules

Each state, enrollment broker and Medicaid plan must continue to provide all beneficiary information in an easily understood and readily accessible manner and format which includes the use of TTY/TDY and American Sign Language interpreters. States need to use the beneficiary support system in the Final Rule to provide education and choice counseling to all beneficiaries. States must develop standardized managed care definitions and terminology and model enrollee handbooks and enrollee notices for use by its contracted plans.

Language and format

The Final Rule largely carries over existing standards for language and formats for beneficiary information. However, CMS adopted three new standards.

1. Materials for potential enrollees disseminated by the state and plans must be available in prevalent languages and include taglines in each prevalent non-English language and large print explaining the availability of written materials in those languages as well as oral interpretation in understanding the materials.
2. Written materials must also be made available in alternative formats and auxiliary aids and services should be made available upon request at no extra cost.
3. Provider directories, member handbooks, appeal and grievance notices and other notices that are critical to obtaining services would have to be made available in each prevalent non-English language in the MCOs service area.

Information requirements

Medicaid plans must provide each enrollee an enrollee handbook, provider directory and formulary information within a reasonable time after receiving notice of the beneficiary’s enrollment.

Enrollee handbook

The Final Rule requires an extensive list of information that the handbook must contain. Examples include: a detailed description of the amount, duration and scope of benefits; how and where to access benefits; after-hours and emergency coverage; cost-sharing; enrollee rights and responsibilities; grievance, appeal and fair hearing procedures; and any other content required by the state.

Provider directories

The Final Rule adds new elements to the minimum content standards for provider directories. The directory must include five provider types (although states can mandate more) if applicable under the contract: physicians, hospitals, pharmacies, behavioral health, and LTSS, as appropriate. In addition to name, address, telephone number and open panel status, the directory is to include: a provider’s group/site affiliation; website URL (if available); the provider’s
cultural and linguistic capabilities, and whether the provider’s office has accommodations for enrollees with physical disabilities.

Paper provider directories must be updated at least monthly and electronic directories within 30 calendar days of receiving updated provider information. The provider directories are to be made available on the plan’s website in a machine readable file and format to be specified by the Secretary. Paper directories must be available upon request and at no extra cost.

**Formularies**

Medicaid plans are required to provide their medication formularies electronically or in paper form, if requested. The formulary must display all covered medications, both generic and brand name, and have the tier of each medication. Similarly, the formulary drug lists must be made available on the plan’s website in a machine readable file and format as specified by the Secretary.

**Communication methods**

The Final Rule provides the flexibility for Medicaid plans to use a range of methods for distributing enrollee materials, such as member handbooks and the provider directory, including through mail, email, and website posting. However, to provide these materials electronically, plans would need to notify enrollees that the materials are available in paper form and through auxiliary aids and services without charge upon request. CMS further specifies that plans can provide enrollee handbooks by mail, email, website with paper and electronic notification along with auxiliary aids and services for enrollees with disabilities who cannot access information online, or by any other method that can reasonably be expected to result in the enrollee receiving the information. The last method is to provide flexibility for communication methods not commonly used, such as alternative devices for persons with disabilities and other technological advances in communication not yet widely available.

- Effective date: no later than the rating period for contracts starting on or after July 1, 2017


CMS recognizes that a different Medicaid primary care case management (PCCM) model, generally referred to as the “enhanced” PCCM model, is being employed by states where more intensive care case management is provided. The Final Rule refers to such models as “primary care case management entities” (PCCM entities) and creates new standards for them. The standards include:

- Requiring reasonable and adequate hours of operation, enrollment restricted to beneficiaries who reside near one of the PCCM entity delivery sites, and a sufficient number of providers to ensure services can be delivered promptly and without compromising the quality of care.
- CMS review and approval of PCCM entity contracts.
State assessments of the PCCM entity’s performance to detect over and under utilization of services; performance measurement using standard measures; and a program review by the state.

State descriptions of how it is assessing the performance and quality outcomes achieved by each PCCM entity (effective no later than the rating period for contracts starting on or after July 1, 2018); and

Allowing the state to have its EQRO perform an external quality review of each PCCM entity (effective no later than the rating period for contracts starting on or after July 1, 2018).

Effective date: unless otherwise indicated, no later than the rating period for contracts starting on or after July 1, 2017.

Choice of MCOs, PIHPs, PAHPs, PCCMs, and PCCM Entities (§438.52)

In previous regulations, states were required to provide enrollees a choice of at least two MCOs, PIHPs, PAHPs or PCCMs if enrollment in such an entity was required. The Final Rule removes the reference to PCCMs. Instead, states that require Medicaid enrollment in a PCCM system are required to give beneficiaries a choice from at least two primary care case managers employed by or contracted with the state. In addition, states that require Medicaid enrollment in a PCCM entity may limit a beneficiary to a single PCCM entity, but beneficiaries must be permitted to choose from at least two primary care case managers employed by or contracted with the PCCM entity. Further, for purposes of the rural area exception to the requirement that an enrollee have the choice of at least two plans, the Final Rule adopts Medicare’s county-based classifications that add information from the Census Bureau. CMS indicated it believes this change will enable more counties to be eligible for the rural exemption. The Final Rule also eliminates the rural exception for PCCMs.

Effective date: 60 days after publication

Non-Emergency Medicaid Transportation PAHPs (§438.9)

The Final Rule applies certain additional provisions to PAHPs that deliver only Non-Emergency Medical Transportation (NEMT) services such as: most of the standard contract requirements; actuarial soundness standards, information standards, anti-discrimination provisions, certain enrollee rights and responsibilities, right to fair hearings, and program integrity standards.

Effective date: 60 days after publication

Encounter Data and Health Information Systems (§438.2, §438.242 and §438.818)

Under the Final Rule, a state must ensure that each Medicaid plan maintains a health information system that collects, analyzes, integrates, and reports data on areas including utilization, claims, grievance and appeals, and disenrollment for other than loss of Medicaid eligibility. The plans must collect data on enrollee and provider characteristics as specified by the state and on all
services furnished to enrollees through an encounter data system. The plans are required to verify the accuracy and timeliness of the reported data, including data from network providers.

CMS intends to review whether the MCOs provide timely and accurate encounter data to facilitate the transition to the new Transformed Medicaid Statistical Information System (T-MSIS) as described in an August 2013 State Medicaid Director Letter. CMS will issue future guidance and revisions to the CMS EQR protocols to reflect this ongoing effort.

The Final Rule also mandates that state claims processing and retrieval systems be able to submit data elements to CMS that are deemed necessary for Medicaid program integrity, oversight, and improvement. Plan contracts must incorporate enrollee encounter data standards and specify that enrollee encounter data must:

- Include rendering provider information
- Be submitted in a manner compliant with CMS specifications
- Be submitted to the state in a format consistent with the industry standard ASC X12N 835 and NCPDP formatting, and ASC X12N 837 as appropriate.

Plans are required to submit the encounter data, on a monthly basis, at a level to be specified by CMS in future clarifying guidance. The initial guidance is to include standards for MCOs to submit to the state: enrollee and provider identifying information; service, procedure and diagnosis codes; allowed/paid enrollee responsibility, and third party liability amounts; and service, claim submission, adjudication, and payment dates. Encounter data submitted to CMS must represent all services received by an enrollee regardless of payment methodology including services sub-capitated by a MCO to a provider.

The state is required to review and validate that the enrollee encounter data collected, maintained, and submitted to the state meets the federal regulatory standards and that the encounter data is accurate and complete. States must have procedures and quality assurance protocols to ensure the encounter data is a complete and accurate representation of the services provided under the contract. CMS will assess a state’s submission to determine if it is in compliance with criteria for accuracy and completeness.

If the state is unable to come into compliance within the time allowed, CMS will take steps to defer and/or disallow all or part of the federal match for the plan contract in question. Only a portion of the capitation payment attributable to that enrollee for the service type of the non-compliant data would be considered for deferral and/or disallowance.

- This section applies to the rating period for contracts with MCOs, PHIPs, PAHPs, and PCCM entities beginning on or after July 1, 2017. Until then states are to continue to comply with §438.242.
Standards for Contracts Involving Indians, Indian Health Care Providers and Indian Managed Care Entities (§438.14)

The Final Rule requires that:

- Each Medicaid plan contract must demonstrate sufficient Indian Health Care Providers (IHCPs) in the managed care network and that Indian enrollees be able to obtain services from them.
- IHCPs are paid for covered services provided to Indian enrollees who are eligible to receive services from such providers whether the IHCP participates in the managed care network.
- Permit an Indian who is enrolled in a non-Indian managed care entity and eligible to receive services from a participating IHCP to choose that IHCP as his or her primary care provider.
- Permit Indian enrollees to obtain covered services from out-of-network IHCPs.
- In any state where timely access to covered services cannot be ensured due to few or no IHCPs, a plan would be considered to have met the standard for adequacy of IHCP providers if either Indian enrollees are permitted to access out-of-state IHCPs or the state deems the lack of IHCP providers to justify good cause for an Indian’s disenrollment from the plan and the managed care program.

The Final Rule also requires that when an IHCP is enrolled in Medicaid as a FQHC but is not a participating provider with a MCO, PIHP, or PAHP, it must be paid FQHC payment rates, including any supplemental payment due from the state. Where the IHCP is not enrolled in Medicaid as a FQHC, the MCO, PIHP or PAHP payment is the same payment as the IHCP would receive under Medicaid FFS program or the applicable encounter rate published by the Indian Health Service.

- Effective date: no later than the rating period for contracts starting on or after July 1, 2017

Emergency and Post-Stabilization Services (§438.114)

The Final Rule clarifies that Medicaid plans are required to follow Medicare Advantage plan guidelines when covering post-stabilization services, but are paid consistent with federal and state Medicaid payments standards, not based on Medicare rates.

- Effective date: 60 days after publication

II. CHIP Requirements

Section 403 of the Children’s Health Insurance Program Reauthorization Act of 2009 applied certain Medicaid managed care provisions to CHIP managed care entities. The Final Rule addresses the application of the managed care provisions to CHIP plans through the creation of a new Subpart L – Managed Care.
Effective date: The effective date for the CHIP provisions (unless otherwise noted below) is no later than state fiscal year beginning on or after July 1, 2018.

Contracting Requirements (§457.950, §457.1201)

CMS adopted several of the Medicaid standards from section §438.3 without modification. These provisions relate to the relevant entities eligible for comprehensive risk contracts, the inclusion of payment rates, prohibitions on enrollment discrimination, complying with applicable laws and conflict of interest safeguards, the inspection and audit of records and access to facilities, physician incentive plans, provider choice, audited financial reports, and some of the additional rules for contracts with PCCMs and PCCM entities. CMS also adopted by reference the new Medicaid provision that requires MCOs to maintain records of audits and other recordkeeping for 10 years.

CMS previously did not require the submission of CHIP managed care contracts for review by CMS. Under the Final Rule, states are required to submit CHIP managed care contracts to CMS but the agency is not applying the Medicaid standards relating to contract pre-approval and rate review. As CMS gains experience from these reviews, the Secretary will specify standards in future subregulatory guidance. Nonetheless, the rule does require that CHIP contracts submitted to CMS include the rate that will be paid to the managed care entity.

Rate Development Standards and Medical Loss Ratio (§457.940, §457.1203, §457.1205)

The Final Rule generally retains the current standards for CHIP managed care rate setting with a major addition: the rule imposes an MLR calculation and reporting requirement and requires rates to be developed to meet a target MLR of at least 85 percent.

Non-Emergency Medical Transportation (NEMT) PAHPs (§457.1206)

CMS adopts the Medicaid standards for NEMT PAHPs (e.g., information standards, anti-discrimination provisions, enrollee rights and protections, right to fair hearings, and certain program integrity standards).

Information Requirements (§457.1207)

The Final Rule requires CHIP MCOs, PAHPs, PIHPs, PCCMs and PCCM entities to provide enrollment notices, informational materials and instructional materials relating to enrollees and potential enrollees as provided in the Medicaid section §438.10.

Requirement related to Indians, Indian Health Care Providers, and Indian Managed Care Entities (§457.1209)

The Final Rule aligns CHIP with new Medicaid provisions (§438.14) that provide guidance on how MCOs are to pay IHCPs for services rendered to Indians enrolled in the MCO.
Managed Care Enrollment (§457.1210), Disenrollment (§457.1212), and Continued Services to Beneficiaries (§457.1216):

The Final Rule establishes standards for a default enrollment process when a state elects to assign beneficiaries to a MCO and requires states to provide potential enrollees informational and instructional materials similar to the Medicaid requirements.

Also, states must follow the Medicaid disenrollment standards provided at §438.56, which requires a change in disenrollment procedures in certain situations. Since individuals have the right to disenroll from their managed care entity and still receive benefits, a state currently providing CHIP benefits through one delivery system must either contract with an additional managed care entity, establish a FFS option, or contract with some or all of the state’s existing Medicaid provider network. Due to limited scope of the statute, this offer of alternative delivery systems does not have to be made at the time of enrollment, but only in the event of an enrollee disenrolling from the state’s managed care entity.

Regarding change in enrollment in CHIP, the rule applies the Medicaid provisions at §438.62 (i.e., “continued services to enrollees” which requires the state to have a transition of care policy to ensure continued access when transitioning from an MCO).

Conflict of Interest Safeguards (§457.1214)

The Final Rule adopts the provision which aligns CHIP with the Medicaid conflict of interest safeguards at §438.58.

Network Adequacy Standards (§457.1218)

The Final Rule requires states to have CHIP network adequacy standards as provided in §438.68, which includes the requirement that states develop time and distance standards for pediatric behavioral health specialists.

Enrollee Rights (§457.1220)

The Final Rule requires states to align CHIP with the Medicaid enrollee rights provisions at §438.100. The Final Rule dropped the proposed CHIP requirement that the state must develop time and distance standards for dental providers and pediatric specialists if covered under the MCO contracts.

Provider-Enrollee Communication (§457.1222)

The Final Rule aligns CHIP with the Medicaid enrollee rights protections for communications between providers and enrollees at §438.102.
Marketing Activities (§457.1224)

The Final Rule aligns CHIP with the Medicaid standards related to marketing at §438.104, which includes the flexibility that a QHP issuer that also operates a CHIP managed care plan may market QHPs to the parents of CHIP eligible children.

Liability for Payment (§457.1226)

The Final Rule aligns CHIP requirements with the Medicaid liability provisions at §438.106.

Emergency and post-stabilization services (§457.1228)

The Final Rule aligns CHIP with the Medicaid emergency and post-stabilization service requirements at §438.114.

Access Standards (§457.1230)

The Final Rule aligns CHIP with Medicaid standards, including availability and accessibility of services standards at §438.206; adequate capacity to serve expected enrollees at §438.207; and coordination and continuity of care standards at §438.208. In addition, CHIP MCOs are required to comply with the coverage and authorization of services standards as provided in §438.210. In a reversal from the proposed rule, CMS adopted the requirement that CHIP MCOs will be held to the same timeframes for making coverage decisions as applied to Medicaid MCOs under §438.210(d).

Structure and Operation Standards (§457.1233)

The Final Rule aligns CHIP requirements with the following Medicaid provisions:
- §438.214 related to provider selection
- §438.230 related to subcontractual relationships and delegation
- §438.236 related to practice guidelines
- §438.242 related to health information systems

Quality Measurement and Improvement (§457.760)

The Final Rule aligns CHIP with the following Medicaid provisions:
- §438.310, which outlines standards for a quality assessment and performance improvement program that states must require of each contracting MCO, PIHP, or PAHP.
- §438.330 where the state must require that each MCO establish an ongoing comprehensive quality assessment and performance improvement program.
- §438.332 which requires states to review the accreditation status of each MCO;
- §438.334 under which states must determine a quality rating for each MCO; and
- §438.340 which requires states to draft and implement a written quality strategy for assessing and improving the quality of health care and services;
External Quality Review (§457.1250)

The Final Rule aligns CHIP with the Medicaid external quality review standards at §438.350, §438.352, §438.354, §438.356, §438.358, part of §438.360, and §438.364. States are allowed to amend current Medicaid EQRO contracts to add CHIP activities. The effective date of §457.1250 that pertains to (§438.358(b)(1)(iv) – mandatory EQR activity of validation of network adequacy – is no later than one year from the issuance of the associated EQR protocol.

Grievances (§457.1260)

The Final Rule aligns CHIP with the Medicaid grievance and appeals sections at subpart F of Part 438. However, the Medicaid requirement for continuation of benefits pending appeal under §438.420 does not apply although the state has the option to continue benefits.

Sanctions (§457.1270)

The Final Rule aligns CHIP with Medicaid subpart I of Part 438 in which states must ensure that MCOs, PAHPs, and PIHPs comply with the sanctions standards.

Program Integrity – Conditions Necessary to Contract as an MCO, PAHP, or PIHP (§457.955, §457.1280, and §457.1285)

The Final Rule adopts nearly all of the Medicaid program integrity standards described in subpart H of Part 38 with the exception of the provision pertaining to actuarial soundness. CMS did not apply the Medicaid actuarial soundness requirements to CHIP plans.

III. Third Party Liability (§433.138(e))

The Medicaid statute requires state Medicaid programs to identify and seek payment from liable third parties (TPL) before billing Medicaid. To support identification of TPL, CMS issued regulatory requirements that states identify all paid claims (indicative of trauma) identified by diagnosis codes found in ICD-9-CM, 800 through 999 except 994.6. An update of this code set, ICD-10, replaced the ICD-9 code set effective October 1, 2015. In the Final Rule, CMS replaced the reference to a specific coding system with a general description of the types of medical diagnoses indicative of trauma for which states are expected to edit claims in their TPL search.

- Effective date: 60 days after publication.

IV. Proposals Not Implemented in the Final Rule

Disenrollment Standards and Limitations (§438.56)

Current rules permit a beneficiary to disenroll from a given MCO without cause during the first 90 days of the beneficiary’s enrollment in that MCO. CMS proposed to limit the 90-day without
cause disenrollment period to the first 90 days of an enrollee’s initial enrollment into any Medicaid plan offered through the state plan; therefore, an enrollee would have only one 90-day without cause disenrollment opportunity per enrollment period. However, CMS did not retain this proposal, and the Final Rule affirms that enrollees may disenroll from a given MCO within the first 90 days of the enrollee’s initial enrollment into that MCO, and from each successive MCO at the enrollee’s discretion.

**Deferral and/or Disallowance of FFP for Non-compliance with Federal Standards (§438.807)**

Previously, CMS has interpreted the statute to require that if the MCO contract as submitted for approval or as administered, including capitation rates, is noncompliant with regulatory requirements, there could be no federal match at all for payments under the contract, even for amounts associated with services for which there was full compliance with all requirements. CMS proposed that deferrals and/or disallowances of the federal match can be targeted under the MCO on a service by service basis. For example, if the violation involved the payment amount associated with coverage of inpatient hospital costs, then federal match for only that portion of the payment would be deferred or disallowed. Such determinations can be made prospectively when the contract or rate certification is submitted for CMS review or retroactively. CMS decided not to implement this requirement in the Final Rule.

**Beneficiary Enrollment Protections (§438.54)**

CMS proposed broad parameters for a state’s MCO enrollment processes. States would have to provide at least 14 calendar days of FFS coverage for potential enrollees to make an active choice of their managed care plan unless the beneficiary makes a choice before the 14 days or is in a service area with one contracted MCO. CMS did not implement this requirement in the Final Rule.

*Mental health parity.* The Final Rule does not address requirements under the Mental Health Parity and Addiction Equity Act of 2008 (MHPEA). Separate requirements under MHPAE were published by CMS on March 30, 2016 and when effective (October 2, 2017) will be codified in a new 42 CFR 438 subpart K.

**Advancing Health Information Exchange (438.208(c))**

In the Final Rule, CMS discusses the advantages of health information technology and the electronic exchange of health information in achieving care coordination but does not impose any new requirements in recognition that information exchange is a developing field. CMS encourages states and MCOs to utilize health information exchange and certified health IT to support the delivery and management of care.

**State Review and Approval of MCOs, PIHPs, and PAHPs (new §438.332)**

CMS proposed but did not implement in the Final Rule a requirement that MCOs undergo an accreditation review as a condition of entering into a contracting relationship with a state that. States were given a choice of two options (or a combination thereof) to comply with the proposed review.
The first option was a state review and approval process based on standards at least as stringent as those used by a private accreditation entity recognized by CMS in Medicare Advantage or the Marketplace. The review and reissue of approval of each MCO would have to be completed at least once every 3 years. MCOs would be required to maintain performance with state standards at the level necessary for approval for as long as they participate in the state’s managed care program.

The second option would allow a state to elect to use evidence that an MCO has obtained accreditation by one of the CMS-recognized private accreditation entities. The MCO would have to authorize the private accreditation entity to provide the state with copies of its most recent accreditation survey.

States could select components of both options. For example, states would be able to establish their own review and approval process and also allow plans that have obtained private accreditation to submit documentation in accordance with the second option. States are to make the final approval status of each MCO publicly available on the state’s Medicaid website, regardless of which option is selected.


Under current regulations states contracting with MCOs must maintain a written strategy for assessing and improving the quality of managed care services offered by MCOs. CMS also proposed to extend the scope of this comprehensive MCO strategy requirement to all state Medicaid programs including FFS Medicaid. The Final Rule retains the requirement for a written strategy for assessing and improving the quality of MCO’s managed care services but CMS determined not to implement the comprehensive strategy requirement in FFS Medicaid.