Summary: Medicaid and CHIP Managed Care Final Rule (CMS-2390-F)
42 CFR Parts 431, 438, 440, 457 and 495

May 13, 2016
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PROVISIONS APPLICABLE TO MEDICAID GENERALLY

42 CFR 433.138(E): THIRD PARTY LIABILITY

- States must identify paid claims that are indicative of trauma, injury, poisoning or other external causes for the purposes of determining the legal liability of third parties so that Medicaid can process claims under third party liability payment procedures.

42 CFR 400.262: CULTURAL COMPETENCY

- States must have methods to promote access and delivery of services in a culturally-competent manner to all beneficiaries.

MEDICAID MANAGED CARE PROVISIONS

- Unless stated otherwise, provisions apply to managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), prepaid ambulatory health plans (PAHPs), primary care case managers (PCCMs) and PCCM entities (referred to in this summary as “plans,” “entities” or “managed care entities”).

42 CFR 438.3: CONTRACTS

- CMS must review and approve all proposed final MCO, PIHP and PAHP contracts.
  o Must be submitted to CMS no later than 90 days prior to the contract effective date.
  o Must specify the final capitation rate.
    ▪ Usually must be based only on Medicaid state plan services in the contract and additional services in the contract that may be necessary to meet mental health parity requirements.
    ▪ Plans can also cover other services but those usually cannot be included in calculating Medicaid capitation rates.
- Specifies what types of entities with which states may enter risk contracts for a comprehensive range of services (MCOs, HIOs, and certain types of health centers).
- Contracts must:
  o prohibit enrollment discrimination (including related to health status);
  o comply with other applicable laws and conflict of interest safeguards (42 CFR 438.58);
  o comply with requirements mandating provider identification of provider-preventable conditions as a condition of payment and the prohibition on payment for provider-preventable conditions;
    ▪ MCOs, PIHPs and PAHPs must report identified provider-preventable conditions to the state.
  o provide for inspection and audit of records and documents and inspection of facilities where Medicaid-related work is done by the state, Centers for Medicare and Medicaid Services (CMS) and Office of the Inspector General (OIG);
  o comply with Medicare Advantage provisions on physician incentive plans (42 CFR 422.208 and 422.210) (MCOs, PIHPs and PAHPs only);
  o in the case of MCOs, PIHPs, and certain PAHPs, comply with Medicare Advantage provisions on written policies and procedures for advance directives (42 CFR 422.128);
  o allow enrollees to choose their own health care providers within the plan’s network; and
  o require MCOs, PIHPs and PAHPs to submit annual audited financial reports in accordance with generally accepted accounting principles (GAAP).
- PCCM contracts must:
  o provide for reasonable and adequate hours of operation including 24-hour availability for emergency services;
  o restrict enrollment in the PCCM to beneficiaries who reside sufficiently near the PCCM delivery site (as defined);
o provide for arrangements with a sufficient number of providers to ensure services can be furnished promptly;
o prohibit discrimination in enrollment based on health status or need; and
o provide disenrollment rights.

- Contracts with PCCM entities must be submitted to CMS for review.
- Contracts with MCOs, PIHPs and PAHPs that cover outpatient drugs must require: compliance with standards in Social Security Act (SSA) section 1927(k)(2) for such coverage and reporting of drug utilization data necessary for states to bill for rebates (excluding 340B drugs); operation of a drug utilization review program and provision of a detailed description of such program activities annually; and operation of a prior authorization program.
- MCOs, PIHPs and PAHPs must enter into Coordination of Benefits Agreements with Medicare and participate in automated claims crossover for Medicare/Medicaid dually-eligible beneficiaries, as applicable.
- An MCO, PIHP or PAHP may cover services or settings in lieu of those covered under the state Medicaid plan, where the state determines such services or settings to be medically appropriate and cost-effective substitutes for services covered under the state Medicaid plan (see also 42 CFR 438.6(e) regarding IMDs).
- MCOs, PIHPs and PAHPs must retain information about enrollee grievances and appeals, base data, MLR reports and other data specified for at least 10 years.

**42 CFR 438.4: CAPITATION RATES**

- Capitation rates for MCOs, PIHPs and PAHPs must be reviewed and approved by CMS as actuarially sound (based on the rates being projected to provide for all reasonable, appropriate and attainable costs required under the terms of the contract and for the time period and population covered).
- Capitation rates must:
  o be developed in accordance with specified rate development standards (42 CFR 438.5) and GAAP;
     Any differences among rates by population must be based on valid rate development standards and must not be based on federal financial participation (FFP) differences.
  o be appropriate for the populations to be covered and services to be furnished;
  o be adequate to meet the requirements relative to availability of services, adequate capacity and services, and coordination and continuity of care (42 CFR 438.206-438.208);
  o be specific to each rate cell (payments for rate cells cannot cross-subsidize one another and must be a specific rate and not a rate range; blended rate structures are permitted);
  o be certified by an actuary working on behalf of the state;
  o meet any applicable special contract provisions relative to incentive arrangements (42 CFR 438.6);
  o be provided to CMS in accordance to the format and timeframe set forth in 42 CFR 438.7; and
  o be develop in a way that will allow the MCO, PIHP or PAHP to reasonably achieve a medical loss ratio (MLR) standard of 85% for the rate year (can be greater than 85% as long as the rate allows for necessary and reasonable administrative costs).
     States should take into account whether a plan met the MLR standard in prior years and include adjustments in rate development going forward as necessary.

**42 CFR 438.5: RATE DEVELOPMENT**

- To set actuarially sound capitation rates, states must complete the following steps (in an appropriate order) or explain why any of these factors are not applicable:
  o identifying and developing base utilization and price data;
  o developing and applying reasonable trend factors (including cost and utilization) to base data developed from experience of the Medicaid population or another similar population;
  o developing appropriate, reasonable and attainable projected costs for the non-benefit component to account for reasonable administrative expenses, taxes, licensing and regulatory fees, reserves,
risk margin, capital costs and other operational costs associated with delivering state plan services;
  o making appropriate and reasonable adjustments to account for changes to the base data, programmatic changes, non-benefit component or other adjustments necessary to establish actuarially sound rates;
  o taking into account historical and projected MLRs; and
  o as applicable, selecting an appropriate risk adjust methodology, applying it in a budget-neutral manner across all MCOs, PIHPs and PAHPs and calculating adjustments to payments as necessary.

- States must provide the three most recent complete years of validated encounter data, FFS data as applicable and audited financial reports to demonstrate experience of the population or a similar population to the actuary developing the rates.
  o Exceptions may be provided based on the unavailability of data; states requesting an exception must set forth a corrective action plan to come into compliance with this requirement within two years.

42 CFR 438.6: INCENTIVE, RISK-SHARING AND WITHHOLD ARRANGEMENTS

- All risk-sharing mechanisms used must be described in contracts and developed in accordance with 42 CFR 438.4, 438.5 and GAAP.
- Incentive arrangements (those under which a contractor may receive additional funds above the capitation rates for meeting specified targets) may not provide for payment in excess of 105% of the capitation rates.
  o Incentive arrangements must: be for a fixed period of time; not be automatically renewable; be made available to public and private contractors under the same terms of performance; not be conditioned on an intergovernmental transfer (IGT) agreement; and be necessary for the specified activities, targets, performance measures or quality-based outcomes that support program initiatives specified in the quality strategy at 42 CFR 438.340.
- If a withhold arrangement (under which a portion of a capitation rate is withheld for meeting specified targets) is included, the capitation payment minus any portion of the withhold that is not reasonably achievable must be actuarially sound. The total withhold must be reasonable and account for the entity’s operating needs taking into consideration enumerated factors.
  o Withhold arrangement must: be for a fixed period of time; not be automatically renewable; be made available to public and private contractors under the same terms of performance; not be conditioned on an IGT agreement; and be necessary for the specified activities, targets, performance measures or quality-based outcomes that support program initiatives specified in the quality strategy at 42 CFR 438.340.
- Except as otherwise specified (such as for Graduate Medical Education (GME) payments), the state cannot direct MCO, PIHP or PAHP expenditures under the contract, including for delivery system and provider payment initiatives generally, except that the state can require such entities to: implement value-based purchasing; participate in a multi-payer delivery system reform or performance improvement initiatives; or adopt a minimum or maximum fee schedule or provide a uniform dollar or percentage increase for particular services across a class of providers.
  o Such contracts must have written prior approval.
    ▪ The state must demonstrate that the arrangement: is based on the utilization and delivery of services; directs expenditures equally across a class of providers; expects to advance the quality strategy in 42 CFR 438.340; has an evaluation plan; does not condition provider participation on IGT agreements; and will not be renewed automatically.
    ▪ Contracts with value-based purchasing or payment delivery system reform or performance improvement initiatives must: make participation in such programs available across a class of providers; use a common set of performance measures; not set the amount or frequency of expenditures; and not allow the state to recoup any unspent funds.
- States may only require MCOs, PIHPs and PAHPs to make pass-through payments (amounts required by the state to be added to the contracted payment rates outside of enumerated purposes) to specified network providers as enumerated and subject to the following phase-out:
  - 10 years for hospitals (through 6/30/2027) according to an enumerated phase-out schedule and subject to transparency requirements.
  - 5 years for physicians and nursing facilities (through 6/30/2022).
  - All contracts that provide for pass-through payments require documentation.
- States may make monthly capitation payments to MCOs or PIHPs for an enrollee aged 21-64 receiving inpatient treatment in an Institution for Mental Diseases (IMD) as long as the facility is a hospital or a sub-acute facility and the length of stay is for no more than 15 days during the monthly capitation payment.

**42 CFR 438.7: RATE CERTIFICATION SUBMISSIONS**
- States must submit for CMS approval all MCO, PIHP and PAHP rate certifications concurrent with the review and approval process for contracts (90 days in advance).
  - Submission must include descriptions of: the base data; each trend factor; the development of the non-benefit component of the rate; all adjustments to develop the capitation rates; risk adjustment methodologies; and any special contract provisions related to payment (42 CF 438.6).
- The state, through an actuary, must certify the final rate paid and document the underlying data, assumptions and methodologies per rate cell.
  - Rates may vary per entity as long as the rates are independently developed and actuarially sound.
  - Any retroactive adjustment must be submitted, supported and certified by an actuary.
    - States may adjust capitation rates within a 1.5% range without submitting a revised rate certification (though the new rate must be submitted to CMS for purposes of claiming FFP).
- CMS may request additional information.

**42 CFR 438.8 AND 438.74: MEDICAL LOSS RATIO**
- Contracts with MCOs, PIHPs and PAHPs that start on or after 1/1/2017 must require entities to calculate and report a medical loss ratio (MLR). The MLR is a tool that requires the actuarial soundness of capitation rates, and will help ensure reasonable, appropriate and attainable costs in providing covered services to enrollees in Medicaid managed care. For multi-year contracts that start prior to 2017, the state must implement such requirement for rating periods beginning 2017.
- If the state elects to mandate a minimum MLR, it must be equal to or greater than 85%.
- In calculating the MLR:
  - the numerator includes incurred claims (as enumerated), expenditures for activities that improve health care quality (as enumerated), and activities compliant with provisions relative to program integrity requirements (as enumerated and excluding fraud reduction efforts; limited to 0.5% of premium revenue).
  - The denominator includes the adjusted premium revenue (as enumerated) minus any federal and state taxes and licensing and regulatory fees.
  - The regulations outline rules for allocating shared expenses and making credibility adjustments.
- If required by the state, a MCO, PIHP or PAHP must provide a remittance for any reporting year for which it does not meet the minimum standard.
- The state must, through its contracts with MCOs, PIHPs or PAHPs, require them to submit reports for each MLR reporting year including the enumerated list of items within 12 months of the end of the year. There will be a one-year MLR reporting year but states have the flexibility to define the reporting year period for purposes of comparing the assumptions in the most meaningful time period for a state.
- The regulations continue to allow value-based purchasing, in particular, for secondary network savings to avoid single case use agreements with providers.
- A state may exclude entities from MLR requirements for their first year of operation.
- The state must annually submit to CMS a summary description of MLR reports with the actuarial rate certifications, including the numerator, denominator, MLR and any remittances owed.
If the state requires remittances for not meeting the minimum MLR, the state must reimburse CMS for the federal share.

42 CFR 438.9: NON-EMERGENCY MEDICAL TRANSPORTATION (NEMT) PAHPS

- NEMT PAHPs must only comply with the following provisions: standard contract provisions (except as they relate to physician incentive plans, advance directives, long-term supports and services (LTSS) requirements and mental health parity); actuarial soundness; information requirements; provisions against provider discrimination; state responsibility provisions relative to disenrollment (as applicable), conflict of interest safeguards, prohibitions of additional payments and continued services (42 CFR 438.56, 438.58, 438.60 and 438.62(a)); certain provisions on enrollee rights and protections; PAHP-specific standards relative to availability of services, coverage and authorization of services, provider selection, confidentiality, subcontracts and health information systems (42 CFR 438.206(b)(1), 438.210, 438.214, 438.224, 438.230, and 438.242); enrollee rights to a state fair hearing; prohibitions against affiliations with individuals debarred or excluded by federal agencies; and requirements relating to contracts involving Indians, Indian Health Care Providers and Indian Managed Care Entities.

42 CFR 438.10: INFORMATION REQUIREMENTS

- States, enrollment brokers, MCOs, PIHPs, PAHPs, PCCM and PCCMs entities must provide information to enrollees and potential enrollees in a manner and format that is easily understood and readily accessible. Information may be provided electronically as long as enumerated standards are met.
  - The state must:
    o utilize its required beneficiary support system and operate a website with information provided either directly or via links to plan websites;
    o develop and require plans to use standard definitions for listed terms and model member handbooks and notices;
    o require, through its contracts, that managed care entities provide the enumerated required information.
    o establish a methodology for identifying prevalent non-English languages (including American Sign Language) spoken by enrollees and potential enrollees in each service area and make written translation available in those languages and oral interpretation available in all languages. All written materials must include taglines in large print and identified languages explaining the availability of translation and interpretation services and choice counseling. The state must require the plans do the same for listed materials. Managed care entities must make written materials available in large print and in alternative formats and auxiliary aids and services available at no cost;
    o make interpretation services available (including for all non-English languages and American Sign Language) at no cost and require managed care entities to do the same;
    o notify potential enrollees, and require managed care entities to notify enrollees, of access services and aid available and how to access them; and
    o provide and require managed care entities to provide all materials in an accessible manner as enumerated.
- Each MCO, PIHP, PAHP and PCCM entity must have in place mechanisms to help enrollees and potential enrollees understand the requirements and benefits of the plan.
- At the time of eligibility to enroll or plan choice, the state or its contracted representative must inform potential enrollees about: their right to disenroll; the basic features of managed care; which populations are not eligible and which are subject to mandatory enrollment or eligible for voluntary enrollment; service areas of coverage; covered benefits; provider directory; formulary; cost-sharing; network adequacy requirements; responsibilities for coordination of care; and quality and performance indicators for each plan.
- MCOs, PIHPs, PAHPs and, when appropriate, PCCM entities, must make a good faith effort to give written notice of terminations of contracted providers within 15 days to enrollees receiving their primary care or regular care from that provider.
- The state must notify all enrollees of their right to disenroll annually, how to disenroll and their alternative options.
- Applicable entities must make physician incentive plans available upon request.
- Managed care entities must provide each enrollee with an enrollee handbook within a reasonable amount of time after enrollment in one of the manners enumerated. Must contain information to enable enrollee to understand how to use the plan including as enumerated. Must notify enrollees in advance of significant changes as defined by the state.
- MCOs, PIHPs, PAHPs and, as appropriate, PCCM entities, must make available up-to-date information about their provider directories and formularies as enumerated, including in a machine-readable file and format. These documents must be made available in hard-copy upon request.

42 CFR 438.12: PROVIDER DISCRIMINATION

- MCOs, PIHPs and PAHPs may not discriminate against providers acting within their scope of license. If an entity declines to include an individual or groups of providers in its provider network, it must give the affected providers written notice of the reasons for doing so.

42 CFR 438.14: INDIANS

- In contracts with MCOs, PIHPs, PAHPs and PCCM entities that have provider networks and enroll Indians, the state must require:
  o the entities to demonstrate that there are sufficient Indian Health Care Providers (IHCPs) in their networks to ensure timely access. If timely access to covered services cannot be ensured due to too few IHCPs, MCOs, PIHPs, PAHPs and PCCM entities will be considered to have met the adequacy standard if Indian enrollees are permitted to access out-of-state IHCPs or the state deems the lack of providers sufficient to justify good cause for an Indian’s disenrollment from managed care.
  o that all IHCPs be paid for covered services provided to Indian enrollees (regardless of whether the IHCP participates in the network) based on the negotiated rate or, in the absence of a negotiated rate, at a rate not less than the level and amount of payment the entity would make to a non-IHCP participating provider. If the IHCP is enrolled in Medicaid as a federally-qualified health center (FQHC) but out of the managed care network, the reimbursement must be equal to in-network FQHC reimbursement (including supplemental payments from the state to ensure the IHCP is reimbursed at the FFS rate). If the IHCP is not enrolled in Medicaid as a FQHC and regardless of whether it is in the managed care network, it must be reimbursed at the Indian Health Service encounter rate or, in the absence of such a rate being published, at the state’s fee-for-service payment rate (or the state must supplement the managed care payment to make up the difference).
  o that payments to IHCPs be timely.
  o that enrolled Indians must be able to choose an IHCP as their PCP.
  o that enrolled Indians must be able to receive services from out-of-network IHCPs.
  o that entities permit an out-of-network IHCP to refer an Indian to a network provider.
- Indian Managed Care Entities (ICMEs) may restrict enrollment to Indians.

42 CFR 438.50: MANDATORY ENROLLMENT

- States that have mandatory MCO, PCCM or PCCM entity enrollment must comply with the following requirements except when mandatory enrollment is under a Medicaid waiver.
  o The state plan must specify the types of entities with which it contracts, the payment method used, whether it contracts on a comprehensive risk basis, and the process the state uses for public input.
  o The state plan must assure the state meets applicable statutory and regulatory requirements including regarding managed care contracts and freedom of choice, and that required groups will be exempt from mandatory enrollment in MCOs, PCCMs and PCCM entities.
42 CFR 438.52: PLAN CHOICE

- In order to mandate enrollment:
  o in an MCO, PIHP or PAHP, the state must give beneficiaries a choice of at least two MCOs, PIHPs or PAHPs.
  o In a PCCM system, the state must give beneficiaries a choice from at least two PCCMs.
  o In a PCCM entity, the state can limit beneficiaries to a single PCCM entity as long as the beneficiaries are permitted to choose from at least two PCCMs employed by or contracted with the PCCM entity.
- A beneficiary can be limited to a single MCO, PIHP or PAHP in a rural area under an approved state plan amendment or waiver, but the beneficiary must be given the choice of at least two PCPs or allowed to obtain services from other providers under enumerated circumstances.
- The state can limit beneficiaries to a single Health Insuring Organization under enumerated circumstances.

42 CFR 438.54: ENROLLMENT

- The state must have an enrollment system for voluntary and mandatory managed care programs.
- Under voluntary programs:
  o The system may provide an enrollment choice period during which beneficiaries may exercise an active enrollment choice as to fee-for-service, managed care, and the plan itself.
  o Under a “passive enrollment process”, the system may enroll beneficiaries and offer a period of time for beneficiaries to make a different choice.
  o The state must provide informational notices clearly explaining the implications to potential enrollees of their not making active choices, enrollment periods, disenrollment options, etc.
  o Informational notices must also include contact information for the beneficiary support system specified in 42 CFR 438.71.
  o The system must provide that beneficiaries already enrolled in a managed care plan are given priority to continue in that plan (if the plan cannot accept everyone seeking enrollment in it).
  o The passive enrollment process must seek to preserve existing provider-beneficiary relationships and relationships with providers that have traditionally served Medicaid beneficiaries.
  o The state may consider additional reasonable criteria under the passive enrollment process that support the objectives of the managed care program and then distribute enrollment equitably among plans.
- Under mandatory programs:
  o If the beneficiary does not make an active choice and the state does not use a passive enrollment process, the potential enrollee will be enrolled into a managed care plan selected through the state’s default process.
  o Passive enrollment and enrollment into default plans must take into account plans’ enrollment capacity.
  o Information notices must be provided as under voluntary programs.
  o As under voluntary programs, beneficiaries already enrolled in a managed care plan are given priority to continue in that plan.

42 CFR 438.56: DISENROLLMENT

- Contracts must specify reasons for which the MCO, PIHP, PAHP, PCCM, or PCCM entity may request disenrollment of an enrollee.

42 CFR 438.58: CONFLICT OF INTEREST SAFEGUARDS

- The state must have conflict of interest safeguards in place related to officers, employees and agents who have responsibilities related to contracting prior to contracting with MCOs, PIHPs or PAHPs. Must adhere to 41 U.S.C. 423.
42 CFR 438.60: PROVIDER PAYMENTS

- The state must ensure that no payments are made to a network provider other than by the MCO, PIHP or PAHP for services covered under the contract with the state except when required by federal law (such as GME payments consistent with the state plan).

42 CFR 438.62: CONTINUED SERVICES

- The state must arrange for Medicaid services to be provided without delay to Medicaid managed care enrollees of a plan with a terminated contract or for any enrollee disenrolled from a plan for any reason other than ineligibility for Medicaid.
- The state must have a transition of care policy in place to ensure continued access to services during a transition from fee-for-service (FFS) to managed care or among managed care organizations if, without such a policy, the enrollee would suffer serious detriment to their health or be at risk of hospitalization or institutionalization. The state must provide for: the enrollee to have access to services consistent with the enrollee’s previous access and to retain the enrollee’s current provider for “a period of time;” the enrollee to be referred to appropriate in-network providers; the state or managed care organization previously providing coverage to provide historical utilization data to the new managed care plan; the new provider(s) to get access to the enrollee’s medical records; and other necessary procedures to ensure continued access to needed services. The state must require MCOs, PIHPs and PAHPs to implement these requirements and the state must make its transition of care policy publicly available.

42 CFR 438.66: STATE MONITORING

- The state must have a monitoring system for all managed care programs, focused on enumerated areas (including specific to LTSS). The state must use data collected to improve managed care performance.
- The state must assess the readiness of each MCO, PIHP, PAHP and PCCM entity (via both a review of documents and an on-site review with interviews) prior to implementing a managed care program, when contracting with a new entity and when any existing entity will cover a new eligibility group (starting at least 3 months prior to these events and finishing in sufficient time to ensure smooth implementation). On-site reviews are not required when new eligibility groups are being added. The assessment must assess capacity in operations / administration, service delivery, financial management and systems management.
  - The assessment must be submitted to CMS in order for CMS to make a determination on the contract or amendment.
- The state must submit to CMS within 180 days after each contract year a report on each managed care program, providing information on and assessment of enumerated areas (applicable annual waiver reports will be deemed to satisfy this requirement) starting the contract year following the release of CMS guidance on the content and form of the report.
  - The report must be posted on the website, provided to the Medical Care Advisory Committee (MCAC) and, if the program includes LTSS, provided to stakeholder consultation groups.

42 CFR 438.68: NETWORK ADEQUACY

- State must develop and enforce network adequacy standards for MCOs, PIHPs and PAHPs.
  - Must develop time and distance standards for the following provider types: adult and pediatric primary care; OB/GYN; behavioral health; adult and pediatric specialists; hospitals; pharmacies; pediatric dental; and other providers that promote the objectives of the Medicaid program.
  - States with managed LTSS must develop time and distance standards for LTSS provider types to which an enrollee must travel for services and for which the provider must travel to deliver services.
  - Standards must cover all covered geographic areas but states can have varying standards based on geographic area.
- In developing network adequacy standards, states must consider: Medicaid enrollment; expected utilization of services; characteristics and health care needs of covered populations; numbers and types
of providers required to furnish the services; numbers of providers who are not accepting new Medicaid patients; location of providers and enrollees (including travel time and ordinary means of transportation); ability of providers to communicate with limited English proficient (LEP) enrollees; and ability of providers to ensure physical access, reasonable accommodations, culturally-competent communications and accessible equipment for enrollees with disabilities. For LTSS services, states must also consider supporting choice of provider, ensuring health and welfare of enrollee and support of community integration, and other considerations in best interest of enrollees.

- Must specify in contracts any standards by which exceptions will be evaluated and approved. Must be based on the number of health care providers in that specialty practicing in the service area.
  - If the state grants an exception, the state must monitor enrollee access on an ongoing basis and include the findings in the report to CMS.
- Network adequacy standards must be published on the Medicaid website and be made available upon request.

42 CFR 438.70: STAKEHOLDER INPUT

- State must ensure that the views of beneficiaries, their representatives, providers, and other stakeholders are solicited and addressed in the design, implementation and oversight of a state’s managed LTSS program.
- The composition of the stakeholder group and the frequency of meetings must be sufficient to ensure meaningful stakeholder engagement.

42 CFR 438.71, 438.810, 438.816: BENEFICIARY SUPPORT SYSTEM

- The state must develop and implement a beneficiary support system. This must include: choice counseling; assistance for enrollees in understanding managed care and assistance for enrollees who use LTSS.
  - Must outreach to beneficiaries and be accessible in multiple ways.
  - Enrollment brokers conducting choice counseling must meet independence and conflict of interest standards.
  - Must provide an access point for complaints and concerns, education on grievance and appeals rights, assistance in navigating grievance and appeals processes, and review and oversight of LTSS program data.
- State expenditures for the use of enrollment brokers are eligible for FFP if: the broker (including brokers’ subcontractors) are independent of the managed care plan and other health care providers; the broker is free from conflict of interest; the broker is not subject to civil monetary penalties (CMPs); the broker has not been excluded from participation under federal programs; and CMS has approved an initial contract or memorandum of agreement (MOA).
- State expenditures for the beneficiary support system are eligible for FFP if: supported by an approved cost allocation plan; there is no duplication in payments for the system; and CMS has approved an initial contract or memorandum of understanding.

42 CFR 438.100: ENROLLEE RIGHTS

- The State must ensure that each plan has written policies regarding enrollee rights and complies (and its employees and providers comply) with federal and state law re: enrollee rights.
- Enrollee rights include: receiving information in an accessible manner (per 42 CFR 438.10); being treated with respect and due consideration for his/her dignity and privacy; receiving appropriate information on available treatment options; participating in health care decisions; being free from restraint or seclusion; receiving a copy of his/her medical records and requesting that such records be amended or corrected; and being furnished health care in accordance with 42 CFR 438.206-.210.
- The state must ensure that an enrollee’s exercise of his/her rights does not adversely affect the way a contract entity, network provider, or the state treats that person.
- The state must ensure that each contracted entity complies with other applicable state and federal laws.
42 CFR 438.102: PROVIDER-ENROLLEE COMMUNICATIONS

- An MCO, PIHP or PAHP may not restrict a provider from advising or advocating for an enrolled patient regarding treatment, information, and right to participate in decision-making.
- An MCO, PIHP or PAHP may refuse to provide counseling or referral services based on moral or religious grounds. The entity must inform the state and enrollees of the services it does not cover at specified times. The state must provide information how to obtain the service.

42 CFR 438.104: MARKETING MATERIALS

- Marketing is defined as a communication by MCO, PIHP, PAHP, PCCM or PCCM entity to a Medicaid beneficiary that is not enrolled with that MCO, PIHP, PAHP, PCCM or PCCM that could reasonably be interpreted to influence the beneficiary to change enrollment to the organization that sent the communication.
  
  - Specifically excluded from the definition of marketing is communications from a Qualified Health Plan (QHP) to Medicaid beneficiaries even if the issuer of the QHP is also an entity providing managed care, as this information regarding both commercial and managed care coverage from a single issuer could be helpful to enrollees and allow for greater continuity of care.
  - Permissible marketing includes social media, information about healthy behavior, and speaking at events where the Medicaid enrollment status of audience is unknown.
  - Contracts with plans must: prohibit the distribution of marketing materials without prior state approval; require distribution of materials to the plan’s entire service area; ensure the plan complies with regulatory information requirements ensuring that the beneficiary receives information to support informed decisions on whether to enroll; prohibit the plan from seeking to influence enrollment; prohibit unsolicited marketing; and specify the methods by which the plan ensures that marketing is accurate and not misleading (including not making statements that a beneficiary must enroll to receive benefits or that the entity is endorsed by state or federal government).
  - The state must consult with MCAC in reviewing marketing materials.

42 CFR 438.106: ENROLLEE LIABILITY

- MCOs, PIHPs and PAHPs must provide that Medicaid enrollees will not be held liable for: its debts; covered services for which the state does not pay the entity; covered services furnished under a contract referral or other arrangement that are not reimbursed; or payments that are in excess of the amount the enrollee would owe if the entity covered the services directly.

42 CFR 438.108: COST-SHARING

- Cost-sharing must comply with Medicaid cost-sharing limitations (42 CFR 447.50 through 447.82).

42 CFR 438.110: MEMBER ADVISORY COMMITTEE

- When LTSS services are included under a risk contract, the state must require the plan to establish and maintain a member advisory committee.
- The committee must include a representative sample of the LTSS populations under the contract.

42 CFR 438.114 EMERGENCY AND POST STABALIZATION SERVICES

- States, if contracted with PCCMs of PCCM entities, or the MCO, PIHP or PAHP must cover and pay for emergency services regardless of whether the providers that furnishes the services are contracted with the entity. The entity may not deny payment if an enrollee had an emergency medical condition, or a representative of the entity instructs the enrollee to obtain emergency services.
- The PCCM, PCCM entity, MCO, PIHP, PAHP or state must not:
  - limit what constitutes an emergency medical condition;
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- refuse to cover emergency services based on the emergency room provider, hospital or agent failing to notifying the enrollee’s primary care provider, MCO, PIHP, PAHP or applicable state entity of the enrollee’s screening and treatment within 10 calendar days of presentation for emergency services;
- hold the enrollee liable for payment of subsequent screening and treatment needed to diagnose the condition or stabilize the patient;
- The PCCM, PCCM entity, MCO, PIHP, PAHP or state must continue coverage and payment until the attending emergency physician or provider treating the enrollee determines the enrollee is sufficiently stabilized for transfer or discharge.

42 CFR 438.116: SOLVENCY

- MCOs, PIHPs and PAHPs that are not federally-qualified HMOs must provide assurances satisfactory to the state that its provision against insolvency is adequate to ensure the Medicaid enrollees will not be liable for debts if the entity becomes insolvent.
- MCOs and PIHPs must meet state solvency standards for HMOs or be licensed by the state as a risk-bearing entity. This does not apply to MCOs or PIHPs that do not provide both inpatient and physician services, are public entities, are FQHCs or controlled by one and meet FQHC solvency standards, or have solvency guaranteed by the state.

42 CFR 438.206: AVAILABILITY OF SERVICES

- The state must ensure that all state plan services are available and accessible in a timely manner to MCO, PIHP and PAHP enrollees and that the provider networks for services meet the state’s standards.
- The state must ensure that each MCO, PIHP and PAHP, as appropriate: maintains and monitors a network of providers that is supported with agreements and is sufficient and accessible; provides female enrollees with direct access to a women’s health specialist; provides for second opinions; provides out-of-network coverage as appropriate at no additional cost to the enrollee; and demonstrates that its network providers are credentialed.
- Managed care plans must adequately and in a timely manner cover services outside of the network when the managed care plan’s network is unable to provide such services.
- The state must ensure that each MCO, PIHP and PAHP ensures timely access to care, promotes the delivery of culturally-competent services, and ensures its network providers are physically accessible.

42 CFR 438.207: ADEQUATE CAPACITY AND SERVICES

- The state must ensure that each MCO, PIHP and PAHP assures and demonstrates that it has the capacity to serve the expected enrollment in its service area in accordance with the state’s standards for access to care. Must demonstrate that it offers an appropriate range of services and that it maintains a sufficient network of providers that are adequate for the anticipated number of enrollees; must submit such documentation upon contracting with the state, annually and at the time of significant change including to services, benefits, service area, provider network or enrollment.
- The state must then submit assurances of compliance to CMS, including documentation of an analysis related to the provider network.

42 CFR 438.208: COORDINATION AND CONTINUITY OF CARE

- The state must ensure that each MCO, PIHP and PAHP implements procedures to deliver care and coordinate services for all enrollees in compliance with enumerated standards. The state may exempt certain PIHPs and PAHPs and MCOs serving dual-eligibles.
- The state must identify people who need LTSS or with special health care needs, and each MCO, PIHP and PAHP must comprehensively assess each identified member and develop a treatment plan if required by the state that meets enumerated standards. This standard is further detailed in 42 CFR 438.68 and subject to quality requirements under 45 CFR 438.340.
- Each MCO, PIHP and PAHP must allow enrollees with special health care needs to directly access specialists as appropriate / needed.

42 CFR 438.210: COVERAGE

- Each contract between a state and an MCO, PIHP or PAHP must: specify and define coverage of required services; cover such services in an amount, duration, and scope that is no less than that for the same services under FFS Medicaid; ensure that such coverage is sufficient to achieve the purpose of the service; not arbitrarily deny or reduce amount, duration or scope of a service solely because of a diagnosis or medical condition; and specify what constitutes “medical necessity” in a manner no more restrictive than under the state Medicaid plan.
- Contracts may permit an MCO, PIHP or PAHP to place appropriate limits on a service based on criteria applied under the state Medicaid plan, such as medical necessity, or for utilization control purposes.
- Contracts must require written policies and procedures governing service authorization.
- Any decision to deny or limit service authorization must be made by an individual with appropriate expertise in addressing the enrollee’s medical, behavioral health, or LTSS needs.
- Notice of adverse benefit determinations must be in writing.
- Service authorization determinations usually must be made within 14 days following receipt of the request for service.
  - An additional 14 day extension may be requested by the beneficiary or the provider, or may be justified by the plan if additional information is needed.
  - Expedited authorizations, within 72 hours, may be requested based on health conditions.
- Contracts must provide that compensation for utilization management activities is not structured to provide incentives to deny, limit or discontinue services.

42 CFR 438.214: PROVIDER CONTRACTING

- The state must ensure that each MCO, PIHP and PAHP implements written policies and procedures for selection and retention of providers, including credentialing policies, nondiscrimination policies and policies to exclude federally “excluded providers.” CMS will defer to the state to ensure compliance with state and federal guidance.

42 CFR 438.224: PRIVACY

- The state must ensure that each MCO, PIHP and PAHP adheres to privacy requirements relative to the use and disclosure of individually-identifiable health information as applicable.

42 CFR 438.230: SUBCONTRACTS

- The state must ensure that if a MCO, PIHP or PAHP subcontracts for the performance of obligations under its contract with the state, the plan subcontracts for those services according to enumerated standards and maintains ultimate responsibility for adhering to and fully complying with all terms and conditions of the plan’s contract with the state.
- The subcontractor must agree to comply with all applicable requirements, such as those pertaining to reporting responsibilities, record-keeping, state and federal audits, etc.
- For audit purposes, subcontractors are subject to a 10-year record retention period.

42 CFR 438.236: PRACTICE GUIDELINES

- The State must ensure, through its contracts, that each MCO, PIHP and PAHP:
  - adopts practice guidelines that: are based on valid, reliable clinical evidence or a consensus of providers in the field; consider the needs of enrollees; are adopted in consultation with contracted providers; and are reviewed and updated periodically as appropriate;
  - disseminates the guidelines to all affected providers and, upon request, to enrollees and potential enrollees; and
bases utilization management decisions, enrollee education, coverage of services and other matters on the guidelines.

42 CFR 438.242: HEALTH INFORMATION SYSTEM (HIS)
- The state must ensure that each MCO, PIHP and PAHP maintains a health information system that collects, analyzes, integrates and reports data, including related to utilization, claims, grievance and appeals, and disenrollments other than for loss of Medicaid eligibility, and meets enumerated standards.
- At a minimum, the state must ensure that system: complies with Section 6504(a) of the ACA; collects enrollee data as specified by the state; ensures accurate data from providers; verifies the accuracy and timing of data submissions; screens the data for completeness; collects provider data in a standardized format; and can be made available to the state and CMS upon request.

42 CFR 438.310-438.370: QUALITY REQUIREMENTS AND ACTIVITIES
- States must require each MCO (including non-exempt Health Insurance Organizations (HIOs)), PIHP and PAHP to implement and maintain specifications for quality assessment and performance improvement programs. Entities must establish and implement an ongoing comprehensive quality assessment and performance improvement program that at a minimum includes: external review; the development of a quality strategy; state review of plan accreditation; and a managed care rating system. States have three years to set and implement the quality rating strategy.
  o CMS, through a public notice and comment period, and states may specify performance measures, a methodology for calculating ratings, and topics for performance improvement projects.
  o A state may apply for an exemption from collecting and reporting on performance measures or performance improvement projects via a written request.
  o At a minimum the state must ensure that each applicable plan: conducts performance improvement projects; collects and submits performance measures; has mechanisms in effect to detect under- and over-utilization and to assess quality and appropriateness of care for enrollees with special health care needs and those using LTSS; participates in state efforts to prevent, detect and remediate critical incidents related to home and community-based waiver programs.
  o Annually each plan must measure and report to the state its performance using standard measures and submit data to the state to enable the state to measure their performance. The state must require entities that provide LTSS services to include measures that assess the quality of life of beneficiaries and outcomes of the plan’s rebalancing and community integration activities for those receiving LTSS.
  o The plans must have an ongoing program of performance improvement projects designed to achieve significant improvement in clinical and nonclinical care, including: measurement of performance; implementation of interventions to improve access to and quality of care; evaluation of effectiveness of interventions; and planning and initiation of activities for increasing and sustaining improvement. The results must be reported.
  o The state may allow those serving only dual-eligibles to substitute a Medicare Advantage quality improvement project.
  o The state must review annually the impact and effectiveness of the quality assessment and performance improvement programs based on measures reporting, outcomes and trended results and the results on supporting community integration for those using LTSS. The state may require that entities have in effect a process for its own such evaluation.
- States must require MCOs, PIHPs and PAHPs to report their accreditation status annually. Those that have been accredited must authorize the release of information about their accreditation review. The statue must make accreditation status information available online.
- Each state contracting with MCOs, PIHPs or PAHPs must have a quality rating system based on clinical quality management; member experience and plan efficacy; affordability and management. The state must collect data on these measures and apply CMS methodology to determine quality ratings.
  o CMS may approve an alternative state quality rating system.
  o States may use the Medicare Advantage five-star rating for plans serving only dual-eligibles.
The state must prominently display quality ratings of entities on its website.

- States contracting with MCOs, PIHPs, PAHPs or PCCM entities must have a quality strategy that addresses the following elements: state-defined network adequacy and availability of services; the state’s quality improvement goals and objectives; quality metrics and performance targets for plans; performance improvement projects; independent reviews for plans; the state’s transition of care policy; the state’s plan regarding health disparities; use of intermediate sanctions; a description of how the state will assess performance and quality outcomes; mechanisms used by the state to comply with requirements related to LTSS; information requirements; and the state’s definition of significant change.

- States must ensure that MCOs, PIHPs and PAHPs undergo external quality reviews (EQR) with sufficient and appropriate information. The results of the review must be made available. The state may require PCCM entities to also undergo EQRs.
  - The state must adopt EQR protocols outlining enumerated criteria for the review.
  - The state must ensure EQR organizations meet enumerated criteria regarding competence and independence.
  - The state must contract with at least one EQR organization via an open, competitive procurement process; EQR organizations may subcontract. EQROs and subcontractors must be independent from the state Medicaid agency and from the MCO, PIHP, PAHP or PCCM entities that they review.
  - Mandatory activities include examining the preceding twelve month period for: validation of performance improvement projects that were underway; validation of performance measures; review of compliance with quality standards; and validation of network adequacy, and a review for the preceding three year period for compliance with quality assessment and performance improvement requirements.
    - The state may use information obtained from a Medicare or private accreditation review to avoid duplication if enumerated standards are met.
  - Optional activities: validation of encounter data; administration or validation of quality of care surveys; calculation of performance measures; conduct of additional performance improvement projects; and conduct of quality studies focused on particular services.
  - The EQR organization may provide technical guidance to groups of plans.
  - The state may exempt an MCO from EQR if the MCO has a current Medicare contract and Medicaid contract that cover all or part of the same geographic region and the Medicaid contract has been in effect for at least two consecutive years during which the MCO was subject to EQR and found to be performing acceptably. To exercise this option, the state must obtain certain information on Medicare or private review findings.
  - The state must include EQR results in an annual detailed technical report (created by EQR organizations) that includes enumerated types of information: including how the data was aggregated and analyzed and conclusions were reached; conclusions for each activity conducted; assessment of each plan’s strengths and weakness related to quality, timeliness and access; recommendations for improvement; comparative information; and an assessment of each entity.
    - The state must make the report available by request and on its website, including in an accessible manner.
    - The information may not disclose the identity of any patient.
    - There is a 75% FFP for expenditures for EQR, including the report, for MCOs-related activities and 50% for activities related to other types of plans.
      - In order to collect the 75% FFP, the state must submit the EQR contracts to CMS for review and approval.

42 CFR 438.400-438.424: GRIEVANCE AND APPEALS SYSTEM

- Each MCO, PIHP and PAHP (other than NEMT PAHPs) must have a system in place to handle appeals of adverse benefit determinations and grievances.
  - Non-emergency medical transportation PAHPs are exempt.
  - There may only be one level of appeal.
- An enrollee may file a grievance (expression of dissatisfaction other than related to an adverse benefit determination) or appeal (of an adverse benefit determination) and, once the beneficiary exhausts that process (including if the plan fails to meet required deadlines), may request a state fair hearing. A provider may file an appeal on an enrollee’s behalf or a grievance or request for a fair hearing with written consent and if the state permits.
  o An enrollee may file a grievance at any time orally or in writing as determined by the state. The grievance may be filed with the state or the MCO, PIHP or PAHP.
  o An enrollee or provider may file an appeal within 60 days following notice of an adverse benefit determination orally or in writing. Unless the enrollee requests an expedited resolution, an oral appeal must be followed by a written, signed appeal.

- States may provide for an optional external review process at no cost and within the timeframes outlined for internal appeals.

- The plans must give enrollees adequate and timely notice of adverse benefit determinations in writing (mailed the same day as the decision is dated) and consistent with accessibility standards (42 CFR 438.10). The notice must meet enumerated content standards including the decision, reason for the determination, information about the right to appeal the plan’s decision and to request a fair hearing (including on an expedited basis) and how to do so and information about the right to benefits pending resolution. Timeliness standards vary by type of denial.

- Plans must give enrollees reasonable assistance in submitting grievances and appeals in an accessible manner.

- Plans must acknowledge receipt of grievances and appeals (including oral inquiries) and have independent decision-makers and health care professionals decide on the grievances and appeal as appropriate. Those deciding on grievances and appeals must take into account all evidence (including new evidence). Plans must provide enrollees a reasonable opportunity to present evidence in person and orally and provide timely copies of the case file.

- States must establish timelines for resolution of grievances and appeals (from the date of oral appeal). Plans must provide notice of resolutions.
  o For standard resolution of a grievance and notice, the state’s timeline may not exceed 90 days.
  o For standard resolution of an appeal and notice, the state’s timeline may not exceed 30 days.
  o For expedited resolution of an appeal and notice, the state’s timeline must not exceed 72 hours.
  o Timelines may be extended for up to 14 calendar days if requested by the enrollee or the plan shows there is a need for additional information and that the delay is in the enrollee’s interest. The plan must make reasonable efforts to give prompt oral notice of the delay and follow-up written notice within two days; the appeal must be resolved as expeditiously as the health condition requires.
  o Plans must have an expedited review process if the plan determines or provider indicates that a standard resolution could seriously jeopardize life, health or ability to attain, maintain or regain maximum function.
    - No punitive action can be taken against a provider requesting expedited resolution.

- States must establish standards for notice of resolution of grievances that meet accessibility standards (42 CFR 438.10). Appeals notices must meet accessibility standards (42 CFR 438.10).
  o Expedited resolutions should also be provided orally.
  o Notices of appeals must include: the results and date of completion; notice of fair hearing rights; and how to receive benefits pending the hearing.

- Enrollees may request state fair hearings only after exhausting the single internal appeals process (receiving notice that the plan appeal upheld the adverse benefit determination or if the plan misses deadlines).
  o The enrollee has 120 days to request a fair hearing following an adverse decision or failure of the plan to adhere to deadlines of the internal appeals process.
  o The plan is a party to the fair hearing.

- Plans must provide information about the grievance system to all provider and subcontractors.

- The state must require plans to maintain records of grievances and appeals – with enumerated information - and review that information.
- The plan must continue the enrollee’s benefits pending appeal and state fair hearing if certain enumerated requirements are met. If the final resolution is adverse to the enrollee, the plan may recover the cost of these services consistent with such standards for FFS services.
- If services are not furnished pending appeal, the plan must authorize services promptly if the adverse determination is reversed, no later than within 72 hours.

42 CFR 438.600-438.610: PROGRAM INTEGRITY

- The state must monitor the compliance of managed care entities with program integrity safeguards.
  - The state must screen, enroll and periodically revalidate all network providers in accordance with Medicaid requirements, including PCCMs and PCCMs entities if the primary case manager is not a Medicaid-enrolled provider. This does not obligate the provider to participate in the fee-for-service delivery system.
    - MCOs, PIHPs and PAHPs may execute temporary provider agreements of up to 120 days pending the outcome of the screening process.
  - The state must review ownership and control disclosures submitted by MCOs, PIHPs, PAHPs, PCCMs, PCCM entities and subcontractors in accordance with Medicaid standards.
  - The state must confirm the identify and exclusion status of MCOs, PIHPs, PAHPs, PCCMs, PCCM entities, subcontractors and any person with ownership or control interest or who is an agent or managing employee via routine checks of listed federal databases upon contracting and at least monthly thereafter. If the state finds a match, it must promptly notify the managed care entity and take action.
  - The state must conduct or contract for an independent audit of the encounter and financial data submitted by MCOs, PIHPs and PAHPs at least every 3 years.
  - The state must receive and investigate whistleblower claims re: MCOs, PIHPs, PAHPs, PCCMs, PCCM entities, subcontractors and network providers.
- The state must post on its website or make available: MCO, PIHP, PAHP and PCCM entity contracts, network adequacy data; the name and title of individuals with ownership or control; and results of audits.
- The state must have in place conflict of interest safeguards consistent with 42 CFR 438.58.
- The state must ensure that MCOs, PIHPs, PAHPs, PCCMs or PCCM entities are not located outside of the US and that no claims paid to a provider, subcontractor or financial institution outside of the US are considered in developing capitation rates (foreign payments can be made for administrative services and emergency services).
- The state must require any MCO, PIHP, PAHP, PCCM or PCCM entity to submit: encounter data; data used to certify actuarially-sound capitation rates; MLR data; data used to determine adequate provisions against the risk of insolvency; documentation on which the state certifies availability and accessibility of services, including network adequacy; information on ownership and control, including from subcontractors; annual report of overpayment recoveries; and any other data related to the performance of obligations under this Part.
  - The plan’s CEO or CFO (or someone who directly reports to them to whom they delegate authority) must certify the data submitted, attesting to their best information, knowledge and belief that the data is accurate, complete and truthful.
- The state must require MCOs, PIHPs, PAHPs and subcontractors delegated responsibility for coverage of services and payment of claims to implement and maintain: arrangements and procedures to detect and prevent fraud, waste and abuse including compliance programs with enumerated elements; provision for prompt reporting overpayments; provision for prompt notification of information received that may affect enrollee eligibility; provision for notification of information received that may affect provider eligibility; provision for a method to verify whether services represented to have been delivered were received; provision for prompt referral of potential fraud, waste or abuse; provision of any suspension of a provider if the state determines there is a credible allegation of fraud; and, in the case of plans receiving annual payments of at least $5,000,000, written policies for employees and contractor or agents related to the False Claims Act and whistleblower protections.
- The state must ensure that all network providers are Medicaid-enrolled (they need not render services to FFS beneficiaries).
The state must ensure that each MCO, PIHP, PAHP, PCCM, PCCM entity and subcontractors provide written disclosures of prohibited affiliations, of ownership and control, and reports overpayments within 60 days. Contracts must address the policy for recoveries made for overpayments to providers by MCOs, PIHPs and PAHPs, including payments made to excluded providers or due to fraud, waste or abuse. Managed care entities must report to the state on recoveries of overpayments and the state must use these results for setting capitation rates.

- Managed care entities must require and have a mechanism for network providers to report and return overpayments due to calculation errors within 60 days.

- MCOs, PIHPs, PAHPs, PCCMs and PCCM entities may not knowingly have a relationships with: a debarred or suspended entity or one excluded from procurement activities under the Federal Acquisition Regulation or under Executive Order No. 12549; an individual or entity affiliated with such a person; or an individual or entity excluded from participation in any federal health care program. Prohibited relationships include: director, officers or partners of the plan; subcontractors; a person with a beneficial ownership of 5% or more; and a network provider, employee or consultant.

- If a plan does not comply, the state must notify the Secretary, may continue the agreement unless the Secretary directs otherwise, but may not renew or extend the agreement unless the Secretary provides a statement to the state and Congress describing compelling reasons for doing so. Such Secretarial actions must be taken in consultation with the Inspector General.

42 CFR 438.700-438.730: SANCTIONS

- Each state that contracts with a MCO must, and each state that contracts with a PCCM or PCCM entity may, establish intermediate sanctions described below if it makes the following determinations based on onsite surveys, complaints, financial status or otherwise:
  - An MCO: fails substantially to provide required, medically necessary services; imposes excessive premiums or charges; discriminates based on health status or need for health care services; misrepresents or falsifies information to CMS, the state, enrollees, potential enrollees or health care providers; or fails to comply with requirements for physician incentive plans.
  - An MCO, PCCM or PCCM entity: has distributed directly or indirectly unapproved marketing materials or materials that contain false or misleading information; or has violated statutory or regulatory standards.

- Sanctions that may be imposed: civil monetary penalties (varying as enumerated); appointment of temporary management for an MCO (if enumerated factors exist and prior to a hearing); granting enrollees the right to terminate enrollment; suspension of new enrollment or payment; and additional sanctions under applicable state statutes or regulation.

  - The state can terminate the contract and enroll the contract enrollees in other plans or provide benefits through other state plan mechanism if the MCO, PCCM or PCCM entity has failed to carry out the substantive terms of its contract or to meet applicable statutory requirements. Before terminating a contract, the state must provide: a pre-termination hearing following written notice of the intent to terminate; reason for termination; time and place of the hearing; decision and effective date. For an affirming decision in a hearing, the state must also give accessible notice to enrollees including their options to continue receiving services.
    - After providing notice of intent to terminate, the state must provide notice to enrollees and allow enrollees to disenroll immediately without cause.
    - Before imposing a sanction, the state must provide timely written notice outlining the basis and nature of the sanction and any appeal rights to the plan and provide notice to CMS (also within 30 days of lifting a sanction).

- The state plan must include a plan to monitor for violations specified above.

- A contract with an MCO must provide that payments for new enrollees will be denied when, and for so long as, payment for those enrollees is denied by CMS.
  - A state may recommend to CMS that it impose the denial of payment sanction on an MCO for violations outlined above. Such determination is adopted by CMS unless CMS reverses or modifies it within 15 days. The state must then provide written notice to the MCO, allow the MCO 15 days to provide evidence in its defense (or 30 days upon MCO request with an adequate explanation and CMS has not determined that the conduct poses a threat to enrollee health or
safety) and provide an informal reconsideration based on the evidence submitted by an independent official, followed by a concise written decision (also forwarded to CMS).

- Based on the state recommendation, CMS may deny payment for new enrollees in enumerated circumstances.
- The sanction will be effective 15 days after notice or the date specified in reconsideration notice.
- CMS may independently provide notice and reconsideration.

42 CFR 438.803-438.818: CONDITIONS FOR FEDERAL FINANCIAL PARTICIPATION (FFP)

- FFP is available for payments under an MCO contract only for periods during which the contract is in effect and meets the following requirements:
  o For comprehensive risk contracts: CMS must have confirmed the contractor meets the definition of an MCO or entities described in 42 CFR 438.3(b)(2) through (b)(5) and the contracts meets all the statutory requirements of SSA section 1903(m)(2)(A) and the applicable requirements of SSA section 1932.
  o Prior approval is required by CMS for any MCO contract that extends for less than one year or has a value equal to or more than $1,000,000 indexed from 1998 based on the consumer price index for all urban consumers.
- CMS may defer and/or disallow FFP under a contract subject to approval if the Administrator finds that the contract is non-compliant with SSA section 1903(m)(2)(A) or applicable requirements in SSA section 1932 or the final capitation rates are non-compliant with regulatory requirements.
- FFP is available for payments under MCO contracts or PIHP, PAHP, PCCM or PCCM entity contracts under a SSA section 1915(b)(1) waiver only if the state excludes from the contracts: an entity that has a substantial contractual relationship either directly or indirectly with an individual convicted of certain crimes described in SSA section 1128(b)(8)(B) or 42 CFR 438.610(a); and an entity that employs or contracts for the furnishing of health care, utilization review, medical social work or administrative services an individual or entity who is disbarred, suspended or excluded from procurement activities or is an affiliate of such a person or would provide services through such an individual or entity.
- State expenditures for enrollment brokers are eligible for FFP only if the broker and its subcontractors are independent and free from conflicts of interest. The initial contract or memorandum of understanding must be reviewed and approved by CMS.
- Under risk contracts, the total amount the state pays for carrying out the contract is a medical assistance cost.
- Under non-risk contracts, the amount the state pays for furnishing medical services is a medical assistance cost; the amount the state pays for performance is an administrative cost.
- State expenditures for independent consumer support services for LTSS services are eligible for FFP if the following conditions are met: costs are supported by an allocation methodology; the services are not duplicative; the entity providing the services meets regulatory standards; and the memorandum of understanding has been approved by CMS.
- FFP is available for expenditures under an MCO, PIHP or PAHP contract only if the state provides sufficient and timely enrollee encounter data to CMS as enumerated.

PROVISIONS APPLICABLE TO CHILDREN’S HEALTH INSURANCE PROGRAM (CHIP) GENERALLY

42 CFR 457.204: WITHHOLDING PAYMENT FOR NON-COMPLIANCE

- CMS may withhold payments to states only if, after giving the state reasonable notice for correction and opportunity for a hearing, the Administrator finds substantial non-compliance with the statute or regulations.
42 CFR 457.940: DELIVERY OF SERVICES

- States must submit to CMS a written assurance that Title XXI services will be provided in an effective and efficient manner and must provide for free and open competition, to the maximum extent practical, in bidding all procurement contracts for coverage and other services.

CHIP MANAGED CARE PROVISIONS

42 CFR 457.1201: CONTRACT REQUIREMENTS

- States must submit MCO, PAHP, PIHP, PCCM and PCCM contracts to CMS for review (prior approval is not required).
- Specifies what types of entities with which states may enter risk contracts for a comprehensive range of services.
- The final contract rates for MCOs, PIHPs and PAHPs must be specifically identified in the contract submitted to CMS for review. The rates must comply with provisions under 42 CFR 438.3(c) regarding capitation rates, except that the rates only need to be submitted, not approved.
- Contracts with MCOs, PAHPs, PIHPs, PCCMs and PCCM entities must comply with prohibitions on enrollment discrimination in accordance with 42 CFR 438.3(d) except regarding voluntary enrollment.
- MCOs, PIHPs, PAHPs may cover services that are not covered under the state plan in accordance with 42 CFR 438.3(e).
- All contracts with MCOs, PAHPs, PIHPs, PCCMs and PCCM entities must comply with federal and state law and regulations regarding conflict of interest safeguards in accordance with 42 CFR 438.3(f).
- Risk contracts must allow for inspection and audit of records and access in accordance with 42 CFR 438.3(h)
- MCO, PAHP and PIHP contracts must provide for compliance relative to physician incentive plans as applicable under 42 CFR 438.3(i).
- The state must ensure through its contracts with MCOs, PIHPs and PAHPs that any subcontracts comply with 42 CFR 457.1233(b).
- Contracts must allow for each enrollee to choose his/her health professional in accordance with 42 CFR 438.3(l).
- Contracts must require MCOs, PIHPs and PAHPs to submit audited financial statements in accordance with 42 CFR 438.3(m).
- Contracts with MCOs, PAHPs and PIHPs must comply with requirements related to parity in mental health and substance use disorder benefits in compliance with 42 CFR 438.3(n).
- A PCCM contract must comply with additional requirements under 42 CFR 438.3(q), except the right to disenroll.
- States must submit PCCM entity contracts to CMS for review. Such contracts must comply with requirements regarding attestations, 42 CFR 457.1240(b), 42 CFR 457.1240(e) and 42 CFR 457.1250(a).
- Contracts with MCOs, PAHPs, PIHPs, PCCMs or PCCM entities must include an attestation to the accuracy, completeness and truthfulness of claims and payment data.
- Contracts with MCOs, PAHPs, PIHPs, PCCMs or PCCM entities must guarantee that the plan will not avoid costs for services covered in its contracts by referring enrollees to publicly supported health care resources.
- MCOs, PIHPs and PAHPs must retain and require subcontractors to retain required information for 10 years.

42 CFR 1203: PAYMENT RATES AND MLR

- A state must use payment rates based on public and private payment rates for comparable services for comparable populations.
  - A state may establish higher rates if necessary to ensure sufficient provider participation or access or to enroll providers with exception efficiency or quality (including through value-based purchasing models).
The rates must be developed to allow the MCO, PIHP and PAHP to reasonably achieve the MLR of 85% and for reasonable administrative costs.

- As requested, the state must provide to CMS a description of the manner in which rates were developed.
- The state must submit a summary description of the MLR reports, except that reports are not submitted with actuarial certifications since those are not required in CHIP.
- The state must ensure that each MCO, PIHP and PAHP complies with MLR requirements under 42 CFR 438.8.

42 CFR 457.1206: NEMT PAHPS

- NEMT PAHPS must only comply with the following provisions: standard contract provisions (except as they relate to physician incentive plans and mental health parity); information requirements; provisions against provider discrimination; state responsibility provisions relative to disenrollment (as applicable), conflict of interest safeguards; prohibition of additional payments and continued services (42 CFR 457.1212, 457.1214 and 457.1216); certain provisions on enrollee rights and protections; PAHP-specific standards relative to availability of services, coverage and authorization of services, provider selection, confidentiality, subcontracts and health information systems (42 CFR 457.1230, 457.1233); enrollee rights to a state fair hearing; prohibitions against affiliations with individuals debarred or excluded by federal agencies; and requirements relating to contracts involving Indians, Indian Health Care Providers and Indian Managed Care Entities.

42 CFR 457.1207: INFORMATION

- Medicaid rules related to enrollment notices, informational materials and instructional materials related to enrollees and potential enrollees (42 CFR 438.10) apply.

42 CFR 457.1208: PROVIDER DISCRIMINATION

- Medicaid rules related to provider discrimination (42 CFR 438.12) apply.

42 CFR 457.1209: INDIANS

- Medicaid rules related to Indians, IHCPs and IMCEs (42 CFR 438.14) apply.

42 CFR 457.1210: ENROLLMENT

- In a state that uses a default enrollment process to assign beneficiaries to a MCO, PIHP, PAHP, PCCM or PCCM entity, the process must: assign beneficiaries to qualified plans (those not subject to intermediate sanctions and with the capacity to enroll beneficiaries); seek to preserve existing provider-beneficiary relationships and relationships with providers that have traditionally served CHIP beneficiaries or, if that is not possible, the state must distribute the beneficiaries equitably; not arbitrarily exclude any plans from being considered and may consider additional reasonable criteria; send confirmation of enrollment within five days of enrollment processing by the state and information about the right to disenroll within 90 days of the effective date of enrollment.
- The state must have an enrollment system under which beneficiaries already enrolled in plans are given priority to continue that enrollment.
- The state must send an informational notice to each potential enrollee including the plans available to the enrollee and explaining how to select a plan, the implications of making or not making an active choice of a plan, the length of the enrollment period and disenrollment policies.

42 CFR 457.1212: DISENROLLMENT

- Medicaid rules related to disenrollment (42 CFR 438.56) apply, except that references to “fair hearings” in those rules should be read to refer to “reviews” described in CHIP rules.
42 CFR 457.1214: CONFLICTS OF INTEREST
   - Medicaid rules related to safeguards against conflicts of interest (42 CFR 438.58) apply.

42 CFR 457.1216: CONTINUED SERVICES
   - Medicaid rules related to continued services to enrollees (42 CFR 438.62) apply.

42 CFR 457.1218: NETWORK ADEQUACY
   - The state must develop network adequacy standards in accordance with 45 CFR 438.68 and ensure through contracts that each MCO, PAHP and PIHP meet such standards.

42 CFR 457.1220: ENROLLEE RIGHTS
   - Medicaid rules related to enrollee rights requirements (42 CFR 438.100) apply.

42 CFR 457.1222: PROVIDER-ENROLLEE COMMUNICATIONS
   - Medicaid rules related to protecting communications between providers and enrollees (42 CFR 438.102) apply.

42 CFR 457.1224: MARKETING
   - Medicaid rules related to marketing activities (42 CFR 438.104) apply.
   - CMS did not finalize the requirement that CHIP consult with the MCAC. The final regulations suggest consultation, but do not require consultation in the review of CHIP plans’ marketing materials.

42 CFR 457.1226: ENROLLEE LIABILITY
   - Medicaid rules relating to enrollees of MCOs, PIHPs and PAHPs not being held liable for services or debts of the plans (42 CFR 438.106) apply.

42 CFR 457.1228: EMERGENCY SERVICES
   - Medicaid rules relating to emergency services being available and accessible to enrollees (42 CFR 438.114) apply.

42 CFR 457.1230: ACCESS, CAPACITY AND COORDINATION AND CONTINUITY OF CARE
   - Medicaid rules apply relating to:
     o services being available and accessible to enrollees (42 CFR 438.206);
     o ensuring that each MCO, PIHP and PAHP has adequate capacity to serve the expected enrollment (42 CFR 438.207); and
     o each MCO, PIHP and PAHP complying with coordination and continuity of care requirements (42 CFR 438.208).
   - The state must ensure that each MCO, PIHP and PAHP complies with the coverage and authorization of services requirements as provided in 42 CFR 438.210, except: as relates to medically necessary services (42 CFR 438.210(a)(5)); notice of adverse benefit determination meeting the requirements of 42 CFR 457.1260; and the timeframes set forth in 42 CFR 438.210(d) (instead those in 42 CFR 457.1160 apply).
   - If states choose to provide CHIP services through managed care, coordination of care standards in 45 CFR 438.208 apply.
42 CFR 457.1233: PROVIDER SELECTION, SUBCONTRACTS, PRACTICE GUIDELINES AND HIS

- Medicaid rules relating to each MCO, PIHP and PAHP complying with provider selection requirements (42 CFR 438.214) apply.
- Medicaid rules relating to subcontractual relationships and delegation requirements (42 CFR 438.230) apply.
- Medicaid rules relating to practice guidelines (42 CFR 438.236) apply.
- Medicaid rules relating to health information systems (42 CFR 438.242) apply.

42 CFR 457.1240: QUALITY

- Medicaid rules relating to establishment and implementation of ongoing comprehensive quality assessment and performance improvement program for the services it furnishes to its enrollees (42 CFR 438.330) apply, except that 42 CFR 438.330(d)(3) re: dual-eligibles.
- Medicaid rules regarding state review of accreditation status of each MCO, PIHP and PAHP (42 CFR 438.332) apply.
- Medicaid rules regarding a quality rating systems (42 CFR 438.334) apply.
- Medicaid rules regarding a managed care quality strategy (42 CFR 438.340) apply.

42 CFR 457.1250: EXTERNAL QUALITY REVIEW

- Medicaid external quality review requirements (42 CFR 438.350, 438.352, 438.354, 438.356, 438.358, 438.364 and 438.360 only regarding nonduplication of activities) apply, except regarding exemption from external quality review (42 CFR 438.362). A state may amend an existing EQR organization contract to include these requirements.

42 CFR 457.1260: GRIEVANCE AND APPEALS SYSTEM

- The state must ensure that its contracted MCOs, PIHPs and PAHPs comply with the grievance and appeals requirements and procedures outlined in Subpart F of Part 438 of Title 42, except 42 CFR 438.420 (continuation of benefits during appeal and state fair hearing). Subpart K of Part 457 governs fair hearings.

42 CFR 457.1270: SANCTIONS

- Medicaid rules in 42 CFR Part 438, Subpart I, which pertain to sanctions on MCOs, apply.

42 CFR 457.1280: CONDITIONS NECESSARY TO CONTRACT

- The state must assure that any entity seeking to contract as a MCO, PAHP or PIHP under a separate child health program has administrative and management arrangements or procedures to safeguard against fraud and abuse, that:
  - enforce MCO, PAHP and PIHP compliance with all applicable federal and state statutes, regulations and standards;
  - prohibit the entities from conducting any unsolicited personal contact with a potential enrollee by an employee or agent for the purpose of influencing the individual to enroll;
  - include mechanisms for the entity to report to the state, CMS or OIG violations of law by subcontractors, providers or enrollees.
- The state may inspect, evaluate and audit MCOs, PIHPs and PAHPs at any time if the state determines there is a reasonable possibility of fraudulent or abusive activity.

42 CFR 457.1285: PROGRAM INTEGRITY

PCG’s team of regulatory experts can help you assess the implications of regulatory changes for your state or entity. Contact Margot Thistle (mthistle@pcgus.com) or Lisa Kaplan Howe (lkaplanhowe@pcgus.com) for more information.