STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

Larry Hogan, Governor - Boyd Rutherford, Lt. Governor - Dennis R. Schrader, Secretary

January 26, 2017

The Honorable Edward J. Kasemeyer
Chair
Senate Budget and Taxation Committee House
3 West Miller Senate Office Bldg.
Annapolis, MD 21401-1991

The Honorable Maggie McIntosh
Chair
Appropriations Committee
121 House Office Bldg.
Annapolis, MD 21401-1991

RE: 2016 Joint Chairmen's Report (p.77) – Report on Impact of Federal Managed Care Organization (MCO) Regulatory Changes on HealthChoice

Dear Chairs Kasemeyer and McIntosh:

Pursuant to the requirements of the 2016 Joint Chairmen's Report (p. 77), the Department of Health and Mental Hygiene submits the enclosed report assessing the impact of recent federal regulatory changes governing Medicaid managed care organizations (MCOs) on the Maryland HealthChoice Program.

In May 2016, the Centers for Medicare and Medicaid Services (CMS) issued a final rule on the *Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability*. Last updated in 2002, the new regulations incorporate changes designed to improve MCO program integrity, performance, and accountability through enhanced oversight in areas including contracting requirements; rate-setting and actuarial soundness; beneficiary information, enrollment, and appeal rights; network adequacy and access; and quality of care.

The Department is pleased to share the enclosed tables, which provide a descriptive overview of the revised federal regulatory requirements, preliminarily assess their impact on existing COMAR regulations, and note applicability to MCO contracts beginning on or after July 1, 2017. If additional information regarding this report is required, please contact Mr. Webster Ye, Director, Office of Governmental Affairs, at (410) 767-6480.

Sincerely,

Dennis R. Schrader
Secretary

Enclosure

cc: Shannon McMahon
Webster Ye
Susan Tucker
Jill Spector
Tricia Roddy

REPORT ON IMPACT OF FEDERAL MANAGED CARE ORGANIZATIONS REGULATORY CHANGES ON MARYLAND'S HEALTHCHOICE PROGRAM

Required by 2016 Joint Chairmen's Report (p. 77)

December 1, 2016

OVERVIEW

The following tables outline the impact of the recently updated federal regulations on Maryland HealthChoice Managed Care Organizations (MCOs). Each revised federal regulation has been assigned to a table according to the time period in which the regulation will go into effect following publication of the final rule: *Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability*. As a whole, the tables provide a general overview of the revised federal regulatory requirements, assess their impact on existing COMAR regulations, and note applicability to MCO contracts.

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Table A. Regulations Effective Immediately

CFR Cite	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
433.15	Rates of Federal Financial Participation for administration.	Revises (b)(10) related to funding for performance of external quality review activities.	No	N/A	No
438.370(a)	Federal financial participation (external quality review).	FFP at 75% rate for external quality review (EQR) expenditures, production of EQR results, and EQR activities set forth in 438.358 performed on MCOs and conducted by external quality review organizations (EQROs) and subcontractors.	No	N/A	No
438.370(b)	Federal financial participation (external quality review).	FFP at 50% for EQR-related activities conducted by non-EQROs, and production of EQR results and activities performed on entities other than MCOs.	No	N/A	No
438.370(c)	Federal financial participation (external quality review).	Before claiming 75% match, States must submit EQRO contracts for review and approval.	No	N/A	No

Table B. Regulations Effective 60 Days Post-Publication

CFR Cite	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
431.200	Basis and scope.	Adds "non-emergency transportation PAHP" (pre-paid ambulatory health plan) to scope of fair hearing regulations.	No	No	No
431.220	When a hearing is required.	Adds "non-emergency medical transportation PAHP" to fair hearing regulations.	No	No	No
431.244	Hearing decisions.	Adds "PAHP" to guidelines for timing of fair hearing decisions.	No	No	No
433.138	Identifying liable third parties.	Removes reference to ICD-9-CM previously in regulation.	No	No	No
438.1	Basis and scope.	Reorganizes and updates statutory bases for managed care regulations to add Section 1903(i)(25), which prohibits payment to a State unless the State provides enrollee encounter data required by CMS. Adds rules for Indian enrollees, Indian health care providers, and Indian managed care providers to Section 1932.	No	No	No
438.2	Definitions.	Added definitions for actuary, choice counseling, enrollee, enrollee encounter data, long-term services and supports, managed care program, material adjustment, network provider, potential enrollee, primary care case management entity,	Unsure	10.09.62.01; 10.09.65.19 series	No

Table B. Regulations Effective 60 Days Post-Publication

CFR Cite	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
		rate cells, and state. Revised definitions for health care professional, non-risk contract, primary care case management, and risk contract.			
438.3(a)	Standard contract requirements.	CMS must review and approve all MCO contracts. Proposed final contracts must be submitted in form and manner established by CMS. For contracts prior to specific effective dates, proposed final contracts must be submitted to CMS no later than 90 days prior to the effective date of the contract.	No	N/A	No
438.3(b)	Standard contract requirements.	Identifies entities eligible for comprehensive risk contracts – including MCOs.	No	N/A	No
438.3(c)	Standard contract requirements.	Final capitation rates must be included in the contract for each MCO, must be based only on services covered under the State plan and services deemed by the State to comply with Mental Health Parity and Addictions Equity Act; rate payments must be adequate for MCO to efficiently deliver covered services in a manner compliant with contract. Capitation payments may only be made by the State and retained by MCOs for Medicaid-eligible enrollees.	Yes	10.09.65.19 series	Yes

Table B. Regulations Effective 60 Days Post-Publication

CFR Cite	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.3(d)	Standard contract requirements.	MCO must accept individuals eligible for enrollment in the order in which they apply without restriction. MCOs will not discriminate on the basis of health status or need for health care services. MCOs will not discriminate on the basis of race, color, national origin, sex, sexual orientation, gender identity, or disability or use a policy or practice that has the effect of discriminating on those identified classes.	Yes	10.09.65.02G(2)	Yes
438.3(e)	Standard contract requirements.	MCOs may cover voluntary services but the costs cannot be included in rate setting. MCOs may cover services that are necessary for the MCO to comply with 438.910 (parity). MCOs may cover services and settings in lieu of what is under the State plan if the State determines it is medically appropriate and cost effective, if the enrollee is not required to use the alternative service or setting, if the approved in lieu of services are authorized and identified in the contract as an optional offering, and the utilization and actual cost of in lieu of services is taken into account in developing the component of capitation rates that represents covered State plan services, unless a statute or regulation explicitly	Yes	10.09.65.19 series	Yes

Table B. Regulations Effective 60 Days Post-Publication

CFR Cite	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
		requires otherwise.			
438.3(f)	Standard contract requirements.	MCOs must comply with all applicable Federal and State laws and regulations including Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, the Rehabilitation Act of 1973, the Americans with Disabilities Act of 1990, and section 1557 of the Patient Protection and Affordable Care Act (ACA). MCOs must also comply with the conflict of interest safeguards in 438.58 and with prohibitions in section 1902(a)(4)(C) applicable to contracting officers, employees, or independent contractors.	Yes	10.09.65.02X	Yes
438.3(g)	Standard contract requirements.	Mandates provider identification of provider-preventable conditions as a condition of payment; MCOs must report all identified provider-preventable conditions in a form and frequency as	No	Currently not in regulation	Yes

Table B. Regulations Effective 60 Days Post-Publication

CFR Cite	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
		specified by the State.			
438.3(i)	Standard contract requirements.	Must comply with physician incentive plan requirements in 422.208 and 422.210. Clarifies that language in those sections that state "MA organization," "CMS," and "Medicare beneficiaries," should be read to refer to MCOs, States, and Medicaid beneficiaries.	Unsure	10.09.65.02U	Yes
438.3(j)	Standard contract requirements.	Requires compliance with advance directive requirements in 422.128 for maintaining written policies and procedures about advance directives; must provide adult enrollees with information on policies and include descriptions of applicable State law; information must reflect changes in State law no later than 90 days after the effective date.	Yes	10.09.65.02F(2); 10.09.66.02B(15)	Yes
438.3(k)	Standard contract requirements.	All subcontracts must fulfill requirements of this part for service or activity delegated under the subcontract in 438.230.	Yes	10.09.65.17	Yes
438.3(l)	Standard contract	Contract must allow each enrollee to choose her or her network provider to the extent possible and	No	10.09.66.05	Yes

Table B. Regulations Effective 60 Days Post-Publication

CFR Cite	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
	requirements.	appropriate.			
438.3(n)	Standard contract requirements.	Parity in mental health and substance use disorder benefits. (2) says, "Any State providing any services to MCO enrollees using a delivery system other than the MCO delivery system must provide documentation of how the requirements of subpart K of this part are met with the submission of the MCO contract for review and approval."	No	N/A	No
438.3(o)	Standard contract requirements.	Long-term supports and services (LTSS) contract requirements	No	N/A	No
438.3(p)	Standard contract requirements.	Health insuring organization special rules	No	N/A	No
438.4(a)	Actuarial soundness.	Definition of actuarially sound capitation rates: "Rates that are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the MCO for the time period and the population covered under the terms of the contract, and such capitation rates are developed in accordance with the requirements in paragraph (b) of this section."	Unsure	10.09.65.19 series	No

Table B. Regulations Effective 60 Days Post-Publication

CFR Cite	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.4(b)(1)	Actuarial soundness.	Rates must have been developed in accordance with 438.5 standards and generally accepted actuarial principles and practices. Any proposed differences among rates according to covered populations must be based on valid rate development standards and not on based on the rate of FFP associated with covered population.	Unsure	10.09.65.19 series	No
438.4(b)(2)	Actuarial soundness.	Rates must be appropriate for the populations to be covered and the services to be furnished under the contract.	Unsure	10.09.65.19 series	No
438.4(b)(5)	Actuarial soundness.	Payments from any rate cell must not cross-subsidize or be cross-subsidized by payments for any other rate cell.	Unsure	10.09.65.19 series	No
438.4(b)(6)	Actuarial soundness.	Rates must be certified by an actuary as meeting the applicable requirements of this part, including that the rates have been developed in accordance with 438.3(c)(1)(ii) and (e).	Unsure	10.09.65.19 series	No
438.5(a)	Rate development standards.	Defines budget neutral, prospective risk adjustment, retrospective risk adjustment, and risk adjustment.	Unsure	10.09.65.19 series	No

Table B. Regulations Effective 60 Days Post-Publication

CFR Cite	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.5(g)	Rate development standards.	Prospective or retrospective risk adjustment methodologies must be developed in a budget neutral manner consistent with generally accepted actuarial principles and practices.	Unsure	10.09.65.19 series	No
438.6(a)	Special contract provisions related to payment.	New regulatory provision. Defines base amount, incentive arrangement, pass-through payment, risk corridor, and withhold arrangement.	Unsure	10.09.65.03B(3); 10.09.65.19-3; 10.09.65.22	No
438.6(b)(1)	Special contract provisions related to payment.	All applicable risk-sharing mechanisms, such as reinsurance, risk corridors, or stop-loss limits, must be described in the contract and must be developed in accordance with 438.4, the rate development standards in 438.5, and generally accepted actuarial principles and practices.	Unsure	10.09.65.22	No
438.6(b)(2)	Special contract provisions related to payment.	Contracts with incentive arrangements may not provide for payment in excess of 105 percent of the approved capitation payments attributable to the enrollees or services covered by the incentive arrangement, since such total payments will not be considered to be actuarially sound. For all incentive arrangements, the contract must provide that the arrangement is (1) for a fixed period of time and performance is measured during the	Unsure	10.09.65.03B(3); 10.09.65.19-3	Yes

Table B. Regulations Effective 60 Days Post-Publication

CFR Cite	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
		rating period under the contract in which the incentive arrangement is applied, (2) not to be renewed automatically, (3) made available to public and private contractors under the same terms of performance, (4) does not condition MCO participation in the incentive arrangement on entering into or adhering to intergovernmental transfer agreements, and (5) necessary for specified activities, targets, performance measures, or quality-based outcomes that support program initiatives as specified in the State's quality strategy at 438.340.			
438.6(e)	Special contract provisions related to payment.	Institutions for Mental Disease (IMD) payments – State may make a monthly capitation payment to an MCO for an enrollee aged 21-64 receiving inpatient treatment in an IMD, so long as it is a hospital providing psychiatric or substance use disorder crisis residential services, and length of stay is short term, for no more than 15 days during the period of the monthly capitation payment. The provision of treatment in an IMD must meet in-lieu-of-service requirements. For rate-setting, states can use this service utilization to develop an inpatient psychiatric or substance use disorder	No	N/A	No

Table B. Regulations Effective 60 Days Post-Publication

CFR Cite	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
		component of the cap rate, but must price utilization at the cost of the same services through providers included under the State plan.			
438.7(a)	Rate certification submission.	Rates must be submitted for review and approval concurrently with the review and approval process for contracts.	Yes	10.09.65.19 series	No
438.7(d)	Rate certification submission.	The State must, upon CMS' request, provide additional information, whether part of the rate certification or additional supplemental materials, if CMS determines that information is pertinent to the approval of the certification under this part. The state must identify whether the information provided in addition to the rate certification is proffered by the State, the actuary, or another party.	Yes	10.09.65.19 series	No

Table B. Regulations Effective 60 Days Post-Publication

CFR Cite	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.12	Provider discrimination prohibited.	MCOs may not discriminate in participation, reimbursement, or indemnification of any provider acting within the scope of their license or certification under applicable State law, solely on the basis of that license or certification. If the MCO declines to include an individual or groups of providers in its provider network, it must give the affected providers written notice of the reason for its decision. MCO must comply with provider selection requirements of 438.214. This provision does not require MCOs to contract with providers beyond necessary to meet enrollee needs, preclude the MCO from using different reimbursement amounts for different specialties or for different practitioners in the same specialty, or preclude the MCO from establishing measures designed to maintain quality of services and control costs and are consistent with its responsibilities to enrollees .	No	10.09.65.02M and N; 10.09.65.17A(2)	No
438.50	State Plan requirements.	A State plan that requires Medicaid beneficiaries to enroll in MCOs must comply with the provisions of this section, except when the State imposes the requirement as part of an 1115 demonstration	No	N/A	No

Table B. Regulations Effective 60 Days Post-Publication

CFR Cite	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
		project or under a 1915(b) waiver.			
438.52	Choice of MCOs, Pre-paid Inpatient Health Plan (PIHPs), PAHPs, Primary Care Case Managers (PCCMs) and PCCM entities.	A State that requires Medicaid beneficiaries to enroll in an MCO must give those beneficiaries a choice of at least two MCOs. The exception is for rural area residents authorized under a state plan amendment under 1932(a), an 1115(a) waiver, or a 1915(b) waiver. Under the rural area exception, the State must let the beneficiary choose from at least two PCPs and obtain services from any other provider if: (1) the service or type of provider is not in the MCO network or (2) the provider opts not to join the MCO network after being given the opportunity to join, and the beneficiary is transferred to a participating provider within 60 calendar days after having the option to choose a participating provider or (3) the plan for moral or religious objections does not provide the service sought by the beneficiary or (4) the PCP or other provider	No	N/A	No

Table B. Regulations Effective 60 Days Post-Publication

CFR Cite	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
		determines the beneficiary needs related services that would subject the beneficiary to unnecessary risk and not all of the related services are available within network, or the State determines other circumstances warrant out of network treatment. Rural area is any county designated as "micro," "rural," or "county with extreme access considerations" by the Medicare Advantage Health Service Delivery reference file for the applicable calendar year. If an enrollee is part of the rural area exception, the State cannot impose on their freedom to change between PCPs in a way that is more restrictive than disenrollment limitations in 438.56(c).			

Table B. Regulations Effective 60 Days Post-Publication

CFR Cite	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.54	Managed care enrollment.	Applies to all managed care programs, regardless of authority. Mandatory managed care program enrollment begins with section (d). Provides for auto-assignment of enrollees who do not actively select an MCO. Informational notices to potential enrollees must include MCOs eligible for selection, instructions on how to select an MCO, the implications of not making a selection, explain the enrollment period and all disenrollment options, include contact information for beneficiary support system, and comply with information requirements in 438.10. Enrollees already enrolled in an MCO must receive priority to stay in the MCO if the MCO does not have capacity to accept all enrollees. For enrollees who are auto-assigned, the MCOs must not be subject to suspended enrollment and have capacity to enroll. Auto-assignment should seek to preserve existing provider-beneficiary relationships and relationships with providers that have traditionally served Medicaid beneficiaries. If not possible, then the State must distribute beneficiaries equally among MCOs available to enroll them. States may not arbitrarily exclude MCOs from being	No	10.09.63.02: Enrollment Broker Contract	No

Table B. Regulations Effective 60 Days Post-Publication

CFR Cite	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
		considered. States may use other factors for default enrollment, including family member preferences, previous plan assignment, quality assurance and improvement performance, procurement evaluation elements, accessibility of provider offices for people with disabilities, and other reasonable criteria.			
438.56	Disenrollment: Requirements and limitations.	Disenrollment regulation – adds managed long-term supports and services (MLTSS) provision but mostly the same.	Yes	10.09.63.06; 10.09.66.05	Yes
438.58	Conflict of interest safeguards.	Requires State safeguards against conflicts of interests with MCO entities and staff.	No	10.09.64.03J	No
438.60	Prohibition of additional payments for services covered under MCO, PIHP or PAHP contracts.	State must ensure no payment is made to a network provider other than by the MCO for services under the contract, except when required by Title XIX, in 42 CFR Chapter IV, or when the State makes direct payments to providers for graduate medical education (GME).	No	10.09.65.02C	No

Table B. Regulations Effective 60 Days Post-Publication

CFR Cite	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.100	Enrollee rights.	Outlines enrollee rights that MCOs and providers must observe and keep policies for. Adds 1557 of the ACA (civil rights provision) to compliance.	Yes	10.09.65.02X; 10.09.66.02B(1)	No
438.102	Provider-enrollee communications.	No changes to regulation.	No	N/A	No
438.104	Marketing activities.	Adds an exclusion for qualified health plans to definition of marketing. Adds a private insurance distinction. Adds email and texting to prohibited cold-call marketing activities.	Yes	10.09.65.23C	No
438.106	Liability for payment.	No changes to regulation.	No	N/A	No
438.108	Cost sharing.	No changes to regulation.	No	N/A	No
438.114	Emergency and post stabilization services.	No changes to regulation.	No	10.09.65.20; 10.09.66.08	No
438.116	Solvency standards.	No changes to regulation.	No	10.09.64.04	No
438.214	Provider selection.	Specifies the credentialing process must address acute, primary, behavioral, substance use disorders, and LTSS providers, as appropriate. All	No	10.09.65.02M; Md. Ins. Art. 15-	No

Table B. Regulations Effective 60 Days Post-Publication

CFR Cite	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
		other provisions the same.		112	
438.224	Confidentiality.	No changes to regulation.	No	Business Associate Agreement (BAA); Maryland Confidentiality of Medical Records Act (MCMRA)	No
438.228	Grievance and appeal systems.	No changes to regulation.	No	10.09.71.02	No
438.236	Practice guidelines.	No changes to regulation.	Yes	10.09.64.09L; 10.09.64.10C	No
438.310	Basis, scope, and applicability.	External quality review provisions. Expanded to include external quality review activities, publishing results of activities. Changes to EQR apply in later rating periods.	Yes	10.09.65.03	No
438.320	Definitions.	Adds definitions for access, health care services, and outcomes. Revises definitions of external	No	10.09.65.03	No

Table B. Regulations Effective 60 Days Post-Publication

CFR Cite	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
		quality review and quality.			
438.352	External quality review protocols.	Specifies the bodies responsible for developing the EQR protocols.	No	N/A	No
438.600	Statutory basis, basic rule, and applicability.	Program integrity regulation. Lists authorities for program integrity activities (e.g., handling overpayments, excluded individuals, the Federal False Claims Act). Delayed implementation of requirements.	No	N/A	No
438.602(i)	State responsibilities.	States must ensure MCOs are not located outside of the US and no claims paid to an MCO, out-of-network provider, subcontractor, or financial institution outside of the US are considered in the development of actuarially sound capitation rates.	Unsure	Unsure	No
438.610	Prohibited affiliations.	Regulation is more specific about excluded individuals and entities, incl. no directors, officers, partners, subcontractors, 5% or more owners, or network providers.	Yes	10.09.64.03; 10.09.65.02	Yes
438.700	Basis for imposition of sanctions.	No changes to regulation except to add PCCM entities.	No	N/A	No

Table B. Regulations Effective 60 Days Post-Publication

CFR Cite	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.702	Types of intermediate sanctions.	No changes.	No	N/A	No
438.704	Amounts of civil money penalties.	No changes.	No	N/A	No
438.706	Special rules for temporary management.	Small language changes but substance is the same.	No	N/A	No
438.708	Termination of an MCO, PCCM or PCCM entity contract.	No changes to regulation except to add PCCM entities.	No	N/A	No
438.710	Notice of sanction and pre-termination hearing.	No changes to regulation except to add PCCM entities.	No	N/A	No
438.722	Disenrollment during termination hearing process.	No changes to regulation except to add PCCM entities.	No	N/A	No
438.724	Notice to CMS.	No changes.	No	N/A	No

Table B. Regulations Effective 60 Days Post-Publication

CFR Cite	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.726	State plan requirement.	No changes.	No	N/A	No
438.730	Sanction by CMS: Special rules for MCOs.	No changes.	No	N/A	No
438.802	Basic requirements.	No changes	No	N/A	No
438.806	Prior approval.	No changes.	No	N/A	No
438.810	Expenditures for enrollment broker services.	Removed choice counseling definition. Adds PCCM entity or other health care provider to scope. No other changes.	No	N/A	No
438.812	Costs under risk and non-risk contracts.	No changes.	No	N/A	No
438.816	Expenditures for the beneficiary support system for enrollees using LTSS.	Not applicable.	No	N/A	No

Table B. Regulations Effective 60 Days Post-Publication

CFR Cite	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
440.262	Access and cultural considerations.	Adds sexual orientation and gender identity to access.	Yes	10.09.66.01	Yes

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.3(h)	Program Integrity.	Inspection and audit of records and access to facilities.	Provides for inspection and audit of any records or documents the MCO or its subcontractors has, and grants access to premises, facilities, and equipment where Medicaid-related activities or work is conducted to the State, CMS, Office of Inspector General, Comptroller General, and their designees. The right to audit exists for 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later.	Yes	10.09.65.02 O, P, Q, Y	Yes
438.3(m)	Rate Setting.	Audited financial reports.	Requires MCOs to submit annual audited financial reports.	No	10.09.65.15	Yes

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.3(s)	Pharmacy.	Requirements for MCOs, PIHPs, or PAHPs that provide covered outpatient drugs.	Contracts requiring MCOs to cover outpatient drugs must include that the coverage complies with section 1927 of the Act, that the MCO reports drug utilization data for states to bill manufacturers for rebates no later than 45 calendar days after each quarterly rebate period (minimum info on total number of units of each dosage form, strength, and package size by national drug code of each covered outpatient drug dispensed or covered by the MCO), MCO must establish procedures to exclude utilization data for drugs subject to 340B discounts from the rebate reports when states do not require submission of managed care drug claims data from covered entities directly, MCO must operate a drug utilization review program, MCO must report on its drug utilization review program activities to the State annually, and the MCO must conduct a prior authorization program.	Yes	10.09.65.15; 10.09.67.04	Yes
438.3(u)	Program Integrity.	Recordkeeping requirements.	MCOs and subcontractors must retain all information for a period of no less than 10 years.	Yes	TBD	Yes
438.4(b)(7)	Rate Setting.	Actuarial soundness; CMS review and	Rates must take into account any special contract provisions impacting rates (e.g., value based purchasing, pass-through payments, withhold	No	N/A	No

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
		approval of actuarially sound capitation rates – meet applicable special contract provisions in 438.6.	arrangements).			
438.4(b)(8)	Rate Setting.	Actuarial soundness; CMS review and approval of actuarially sound capitation rates – provided in format and timeframe that meets 438.7.	To have rates approved by CMS, they must comply with format and timeframe requirements.	No	N/A	No

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.5(b)	Rate Setting.	Rate development standards – process and requirements for setting actuarially sound capitation rates.	Rates must comply with provisions in remainder of 438.4 and 438.8 to be considered actuarially sound.	No	N/A	No
438.5(c)	Rate Setting.	Rate development standards – base data.	CMS requires states to submit validated encounter data and audited financial reports for at least the three most-recent and complete years prior to the rating period. Exceptions apply for states that do not have three complete years under managed care.	No	N/A	No
438.5(d)	Rate Setting.	Rate development standards – trend.	Trending must be based on experience, reasonable, and developed in accordance with Generally Accepted Accounting Principles (GAAP).	No	N/A	No
438.5(e)	Rate Setting.	Rate development standards –	This component of the rate must include expenses related to MCO administration, taxes, licensing and regulatory fees, and contribution to reserves, risk	No	N/A	No

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
		non-benefit component of the rate.	margin, cost of capital, and other operational costs associated with providing Medicaid services under the contract.			
438.5(f)	Rate Setting.	Rate development standards – adjustments.	Adjustments must support development of an accurate base data set, address programmatic changes, reflect the health status of the enrolled population or non-benefit costs, and be developed with GAAP.	No	N/A	No
438.6(b)(3)	Rate Setting.	Withhold arrangements.	Capitation payments minus any portion of the withhold that is not reasonably achievable must be actuarially sound. Data related to determining the withhold must be submitted to CMS. Contracts must provide withholds are for a fixed period of time, measured during the rating period of the contract, not automatically renewed, made available to public and private contractors under the same terms of performance, does not condition entering into or adhering to intergovernmental transfer agreements, and necessary for the state's quality strategy.	No	N/A	No
438.6(c)	Rate Setting.	Delivery system and provider	Generally states may not direct MCO expenditures under the contract, but they can require MCOs to	No	N/A	No

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
		payment initiatives under MCO, PIHP, or PAHP contracts.	implement provider value based purchasing models, to participate in multi-payer or delivery system reform or performance improvement initiatives, adopt a minimum fee schedule for network providers who provide particular services, provide uniform dollar or percentage increases for network providers that provide particular services, adopt a maximum fee schedule for network providers who provide particular services so long as the MCO can reasonably manage risk and achieve goals of contract. CMS must approve these arrangements in writing and the state has to demonstrate the arrangements meet certain requirements.			
438.6(d)	Rate Setting.	Pass-through payments under MCO, PIHP, or PAHP contracts.	States may require MCOs to make pass-through payments to network providers that are hospitals, physicians, and nursing facilities. For hospitals, these payments must be phased out in 10 years and reduce annually. For physicians and nursing facilities, these payments must be phased out in 5 years.	No	N/A	No
438.7(b), (c)(1),	Rate	Rate certification	Rate certification submissions to CMS must include base data, trending, the non-benefit component of	No	N/A	No

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
(c)(2)	Setting.	submission.	the rate information, rate adjustment information, risk adjustment information, and special contract provision information. The state can pay different MCOs different rates so long as the rates are set appropriately. Retroactive capitation rate adjustments must be supported by rationale for its reasonableness, certified by an actuary, and submitted to CMS as a contract amendment. This submission is subject to federal timely filing requirements.			

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.8	Rate Setting.	Medical loss ratio standards.	MCOs must calculate and report medical loss ratio (MLR) to the State. If State establishes a minimum MLR, it must be equal to or higher than 85%. Sets standards for numerator and denominator of calculating MLR. Permits MCOs to add a credibility adjustment under specific circumstances. If the MCO does not meet the MLR, and the state requires it, the MCO must provide a remittance. The State must require the MCO to submit a report that includes at least the following: total incurred claims, expenditures on quality improvement activities, expenditures related to program integrity, non-claims costs, premium revenue, taxes, licensing fees, regulatory fees, methodologies for allocation of expenditures, any credibility adjustments applied, calculated MLR, remittance (if applicable), comparison of information reported to audited financial report, description of aggregation method, and the number of member months. A state can exclude an MCO from the MLR requirement during its first year of operation. For retroactive changes to capitation payments for a MLR reporting year where the report has been submitted to the state,	No	N/A	No

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
			the MCO must recalculate the MLR and resubmit the report to the state. MCOs must attest to all MLR calculations when submitting reports.			

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.10	Information.	Information requirements.	Defines limited English proficient, prevalent, and readily accessible. Requires providing info in an easily understood and readily accessible way to enrollees and potential enrollees. State may link to MCO website info. State must develop standard definitions for managed care terms, model enrollee handbooks, and enrollee notices. MCOs may provide electronic info, but MCOs must provide paper copies within 5 business days of request. MCOs must help enrollees and potential enrollees understand plan requirements and benefits. Written materials must include taglines in large print (18 pt or larger) explaining oral or written translation is available, along with the toll-free number. MCOs must make written materials critical to obtaining services available in prevalent non-English languages in its service area, alternative formats, and auxiliary aids and services, at no cost to the enrollee. All material fonts must be 12-pt. or greater. Potential enrollees must receive info about right to disenroll, managed care, excluded populations, MCO service areas, MCO covered benefits, State-covered benefits, counseling or referral services for services MCOs do not provide	Yes	10.09.62.01, 10.09.63.02, 10.09.63.05, 10.09.65.02, 10.09.65.17, 10.09.66.01, 10.09.66.02, 10.09.67.04, Enrollee Handbook template	Yes

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
			for moral or religious objections, provider directory and formulary info, cost-sharing, network adequacy/access info, coordination of care and MCO quality indicators. The MCO must give written notice about a termed provider to enrollees within 15 calendar days. States must notify enrollees of right to disenroll annually. The MCO must share upon request physician incentive plan info. Requirements for enrollee handbooks, provider directories, and formularies.			
438.14	Indian Enrollees.	Requirements that apply to managed care contracts involving Indian enrollees, Indian Health Care Providers (IHCPs) and Indian Managed Care Entities (IMCEs).	Contracts must require MCOs to demonstrate there are sufficient Indian health care providers participating in the network to ensure timely access to services available under the contract for Indian enrollees eligible to receive them; require IHCPs are paid for covered services to Indian enrollees, whether they participate in the network or not, at a negotiated rate or a rate not less than the level and amount of payment the MCO would make for a non-IHCP; make payments to IHCPs in a timely manner; permit Indian enrollees to choose IHCPs as PCPs so long as they have capacity; permit Indian enrollees to obtain services from out-of-network IHCPs. Adequate access is provided if a state with	Yes	N/A	Yes

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
			few or no IHCPs permits Indian enrollees to access out-of-state IHCPs or consider it good cause for disenrollment. MCOs must permit out-of-network IHCPs to refer Indian enrollees to network providers. IHCPs that are also federal-qualified health centers (FQHCs) must be reimbursed comparably to other FQHCs, including supplemental payments. IHCPs have the right to receive the applicable encounter rate published annually by the Indian Health Service, or in the absence of a published rate, the FFS Medicaid rate.			
438.66(a)-(d)	Program Integrity.	State monitoring requirement; readiness reviews.	Requires the state to have a comprehensive monitoring system. For new MCOs or when MCOs provide benefits to new eligibility groups, the state will be required to conduct a readiness review at least 3 months prior to the effective date and submit it to CMS with the new contract or amendment. Readiness reviews must include desk reviews and onsite reviews for new MCOs and may include only desk reviews for MCOs adding new eligibility groups. Review must address operations/administration, service delivery, financial management and systems management.	No	10.09.64	No

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.74	Rate Setting.	State oversight of the minimum MLR requirement.	The state must submit a summary description of the MLR reports with the rate certification. If the state requires remittances, it must reimburse the federal share of the remittance, taking into account the federal match. The state must submit a separate report with the methodology for calculating the federal and state share of the remittance.	No	N/A	No
438.208	Care Coordinatio n.	Coordination and continuity of care.	MCOs must have procedures to deliver care to and coordinate services for all enrollees. MCOs must ensure enrollees have people or entities designated as primarily responsible for coordinating their services, along with contact info for people or entities. MCO must coordinate services between settings of care (including appropriate discharge planning for short-term and long-term hospital and institutional stays), with services enrollees receive from other MCOs, FFS Medicaid, and community and social support providers. MCOs must make a best effort to conduct an initial screening of each enrollee's needs within 90 days of the effective date of enrollment for all new enrollees and share with the State or other MCOs to avoid duplication of activities, ensure provider has an enrollee health	Yes	10.09.63.03; 10.09.65.04; 10.09.66.07	Yes

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
			record, and ensure enrollee privacy is protected. The state must have mechanisms to identify people with special health care needs and may use state staff, the enrollment broker, or MCOs. MCOs must comprehensively assess enrollees with special health care needs to identify any ongoing special conditions that require a course of treatment or care monitoring using appropriate providers. MCOs must produce a treatment or service plan if the state requires it, developed by a service coordinator with providers caring for the enrollee, trained in person-centered planning, approved by the MCO if required, in accordance with quality assurance and utilization review standards, and reviewed and revised upon reassessment of functional need at least every 12 months (or when the enrollee's circumstances/need changes or the enrollee requests it). MCOs must have mechanism for enrollees with special health care needs to directly access a specialist as appropriate (e.g., standing referral or approved number of visits).			
438.210	Care Coordinatio	Coverage and authorization of	Contracts must identify, define, and specify the amount, duration, and scope of each service the MCO is required to offer; require services to be	Yes	10.09.65.02; 10.09.71.02; 10.09.71.04;	Yes

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
	n.	services.	furnished in an amount, duration, and scope no less than that provided in FFS Medicaid; provide MCOs ensure services reasonably achieve purpose for which they are furnished; provide MCOs cannot arbitrarily deny or reduce required services because of diagnosis, type of illness, or enrollee's condition; permit MCOs to place limits on services based on criteria under the state plan, such as medical necessity or for utilization control purposes; specify what constitutes medically necessary services; require policies and procedures for service authorization; require notice to the enrollee and requesting provider of an adverse benefit determination; set timeframes for standard authorization decisions that do not exceed 14 calendar days after service request, with allowances for a 14 day extension if the enrollee or provider requests it or the MCO justifies the extension is in the enrollee's interest and more info is needed; provide expedited authorization decisions must be made no later than 72 hours of the service request, and may be extended up to 14 calendar days; provide notice of covered outpatient drug authorization decisions as provided in section		10.09.71.05	

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
			1927(d)(5)(A); and ensure individuals or entities making utilization management decisions are not incentivized to deny, limit, or discontinue medically necessary services to any enrollee.			
438.230	Program Integrity.	Subcontractual relationships and delegation.	Requires contracts to state that MCO maintains ultimate responsibility for compliance with State contract. Subcontracts must spell out delegated activities or obligations, and related reporting; subcontractor agrees to perform duties in accordance with MCO's contract obligations, and a subcontract must provide for revocation or other remedies if subcontractor has not performed satisfactorily. Right to audit, evaluate, and inspect subcontracts includes books, records, contracts, computer or other electronic systems, and any contractor of the subcontractor. Right to audit lasts 10 years. Subcontractor must make available premises, physical facilities, equipment, books, records, contracts, computer or other electronic systems relating to its Medicaid enrollees. If there is a reasonable possibility of fraud or similar risk, the subcontractor may be inspected, evaluated, and audited at any time.	Yes	10.09.65.02Y, 10.09.65.17	Yes

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.242	Information Technology.	Health information systems.	MCOs must have a health information system that collects, analyzes, integrates, and reports data on utilization, claims, grievances and appeals, and disenrollments for reasons other than loss of Medicaid eligibility, etc. At a minimum, MCOs must comply with Section 6504(a) of the ACA, collect data on enrollee and provider characteristics and on all services furnished to enrollees through an encounter data system, ensure data collected is accurate and complete, and make all data available to the state and upon request to CMS. Encounter data must identify the provider who delivers any items or services to enrollees; be submitted to the state at a frequency and level specified by the state and CMS based on administration, oversight, and program integrity needs; include information required by 438.818; and identify encounter data specifications. State must review and validate encounter data submitted by the MCO in accordance with its procedures and quality assurance protocols to ensure that it is a complete and accurate representation of the services provided to the enrollees.	Yes	10.09.64.11; 10.09.65.15	Yes

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.330	Quality.	Quality assessment and performance improvement program.	Contract must require MCO establish and implement an ongoing comprehensive quality assessment and performance improvement program. CMS may specify performance measures and PIPs for MCOs to do; however, states may request exemptions from requirement in writing. Quality assurance and performance improvement (QAPI) must include at a minimum performance improvement projects (PIPs), performance measurement data collection and submission, detection of utilization patterns, and mechanisms to assess the quality and appropriateness of care for people with special health care needs. States must identify standard performance measures relating to performance of MCOs, including any specified by CMS and require annual reporting of data to calculate performance measures. State must require MCOs conduct PIPs that focus on both clinical and nonclinical areas. State must review at least annually the impact and effectiveness of the QAPI based on performance measures and PIPs and may require the MCOs to develop a process to evaluate its own QAPI.	No	10.09.65.03	Yes

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.332	Quality.	State review of the accreditation status of MCOs, PIHPs, and PAHPs	State must require MCOs to inform if they are accredited by a private entity and authorize the entity to provide the state a copy of its most recent review, including the status, survey type, level, results (including recommended actions or improvements, corrective action plans (CAPs), and summaries of findings), and expiration date. State must make accreditation status available on the website, and update information at least annually.	Yes	10.09.65.03	Yes
438.400	Appeals and Grievances.	Subpart F; statutory basis and definitions.	Provides definitions for the following terms: adverse benefit determination (ABD), appeal, grievance, grievance and appeal system, and state fair hearing.	Yes	10.09.62.01	Yes
438.402	Appeals and Grievances.	Subpart F; general requirements.	MCOs must have a grievance and appeal system. MCOs must have one level of enrollee appeals. Enrollees have the authority to file grievances and request appeals. If the ABD is upheld, the enrollee can request a state fair hearing. If MCO fails to adhere to notice and timing requirements, the enrollee can initiate a state fair hearing. States have the option of arranging for external medical reviews at the enrollee's request. Grievances may be filed at any time. Appeals may be filed 60	Yes	10.09.71.02; 10.09.71.05	Yes

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
			calendar days from the date on the ABD notice. Enrollees may file a grievance orally or in writing with the state (at the state's option) or with the MCO. Enrollees may request an appeal orally or in writing. Unless the enrollee requests an expedited resolution, oral appeals must be followed by a written, signed appeal.			
438.404	Appeals and Grievances.	Timely and adequate notice of adverse benefit determination.	MCOs must provide timely and adequate notice of ABD, consistent with readability and accessibility guidelines. Describes what must be present in the ABD notice. Outlines the timing of mailing the notice, depending on the ABD.	Yes	10.09.71.05	Yes
438.406	Appeals and Grievances.	Handling of grievance and appeals.	MCOs must give enrollees "any reasonable assistance in completing forms and taking other procedural steps related to a grievance or appeal." MCOs must acknowledge receipt of grievances and appeals, set guidelines about who can make decisions on grievances and appeals, treat oral requests for appeals as the start of the appeal clock and confirm the request in writing unless appeal is expedited, provide enrollee the opportunity to make legal and factual arguments in person or in writing, provide the case file (including medical	Yes	10.09.71.02; 10.09.71.05	Yes

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CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
			records, documents, records, and any new or additional evidence considered, relied upon, or generated by the MCO) free of charge and sufficiently in advance of resolution timeframes, and include the enrollee/representative/enrollee's estate as parties to the appeal.			
438.408	Appeals and Grievances.	Resolution and notification: grievances and appeals.	Grievances must be resolved within 90 calendar days of receipt. Appeals must be resolved within 30 calendar days of receipt. Expedited appeals must be resolved within 72 hours of receipt. Provides guidelines for extensions and notice obligations if the timeframe is extended by the MCO. Appeals process is considered exhausted if timeframes are not met. State must establish the method for notifying enrollee of grievance resolution. Outlines the content of the appeal resolution notice. State fair hearings must be requested within 120 calendar days of the notice of resolution. Parties to the state fair hearing are the MCO and the enrollee/ representative/ enrollee's estate.	Yes	10.01.04.02; 10.01.04.04; 10.09.71.05	Yes

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.410	Appeals and Grievances.	Expedited resolution of appeals.	MCO must establish and maintain an expedited review process for appeals. The standard is "taking the time for a standard resolution could seriously jeopardize the enrollee's life, physical or mental health, or ability to attain, maintain, or regain maximum function." MCOs must ensure providers are not punished for requesting expedition or supporting an enrollee's appeal. If the request for expedition is denied, the MCO must switch the timeframe to a standard resolution and alert the enrollee according to 438.408.	Yes	10.09.71.05	Yes
438.414	Appeals and Grievances.	Information about the grievance system to providers and subcontractors.	MCO must provide certain information about the grievance and appeal system to all providers and subcontractors when they enter into a contract.	Yes	10.09.65.17	Yes
438.416	Appeals and Grievances.	Recordkeeping requirements.	States must require MCOs to maintain records of grievances and appeals for monitoring purposes and for updates and revisions to the quality strategy. Records must contain at a minimum a general description of the reason for the appeal or grievance, the date received, the date of each	Yes	10.09.71.02	Yes

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
			review/review meeting, resolution at each level of the appeal or grievance, date of resolution at each level, and the name of the covered person for whom the appeal or grievance was filed. Records must be accurately maintained, accessible to the state, and available upon request to CMS.			

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.420	Appeals and Grievances.	Continuation of benefits while the MCO, PIHP, PAHP appeal and the State fair hearing are pending.	Timely filing for continuation of benefits is filing on or before 10 days of the MCO sending the notice of ABD or the intended effective date of the MCO's ABD, whichever is later. MCO must continue the enrollee's benefits if the appeal was timely filed; the appeal involved the termination, suspension, or reduction of previously authorized services; an authorized provider ordered them; the period covered by the original authorization has not expired; and the enrollee timely files for continuation. Benefits must be continued until the enrollee withdraws the appeal or fair hearing request, the enrollee fails to request a fair hearing or timely file for continuation, or the state fair hearing rules in favor of the MCO. Depending on the state, if the ruling favors the MCO, the MCO can recover the cost of the services rendered during the hearing.	Yes	10.09.71.05	Yes
438.424	Appeals and Grievances.	Effectuation of reversed appeal resolutions.	If the MCO or fair hearing officer reverses a decision to deny, limit, or delay services, the MCO must authorize the services no later than 72 hours from the date it receives the reversal. If the MCO or	Yes	10.01.04.08; 10.09.71.05	Yes

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
			State reverses a decision to deny authorization of services and the enrollee received the services while the appeal or hearing was pending, the MCO or State must pay for the services.			
438.602(a)	Program Integrity.	State responsibilities – monitoring contractor compliance.	Requires the state to monitor MCO compliance with all program integrity provisions.	No	N/A	No
438.602(c)	Program Integrity.	State responsibilities – ownership and control information.	State must review ownership and control disclosures submitted by MCOs and any subcontractors.	Yes	10.09.65.17	Yes
438.602(d)	Program Integrity.	State responsibilities – federal database checks.	State must perform exclusion checks on MCOs, any subcontractors, and any person with an ownership or control interest, or who is an agent or managing employee of the MCO entity. Must check Social Security Administration Death Master File, National Plan and Provider Enumeration System, List of Excluded Individuals and Entities, System for Award Management, and any other databases the State or	No	N/A	Yes

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
			Secretary may prescribe. If a party is excluded, the State must notify the MCO and take action consistent with 438.610(c).			
438.602(e)	Program Integrity.	State responsibilities - periodic audits.	State must conduct or contract for the conduct of an independent audit of encounter and financial data at least once every 3 years.	No	N/A	No
438.602(f)	Program Integrity.	State responsibilities – whistleblowers.	State must receive and investigate information from whistleblowers relating to the integrity of MCOs, subcontractors, or network providers receiving Federal funds.	No	N/A	No
438.602(g)	Program Integrity.	State responsibilities – transparency.	State must publish the contracts, network adequacy documentation and documentation related to availability and accessibility of services, ownership and control information for MCOs and subcontractors (names and titles only), and the results of financial and encounter data audits.	No	N/A	No
438.602(h)	Program Integrity.	State responsibilities - contracting integrity.	State must have in place conflict of interest safeguards described in 438.58 and must comply with the requirement described in Section 1902(a)(4)(C).	No	10.09.65.28	Yes

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.604	Program Integrity.	Data, information, and documentation that must be submitted.	State must require MCOs to submit the following data: encounter data; data for calculating actuarially sound rates; data for calculating MLR; documentation for compliance with accessibility and availability of services, including network adequacy; ownership and control information for MCO and subcontractors; annual report of overpayment recoveries; any other data, documentation, or information relating to the performance of the entity's obligations.	No	10.09.64.03; 10.09.64.05; 10.09.64.06; 10.09.64.11; 10.09.65.02; 10.09.65.15; 10.09.66.01; 10.09.66.05; 10.09.66.06; 10.09.66.07; 10.09.66.08	TBD
438.606	Program Integrity.	Source, content, and timing of certification.	Data, documentation, and information specified in 438.604 must be certified by the CEO, CFO, or an individual who reports to the CEO or CFO with delegated authority to sign for the CEO or CFO. Certification must attest that based on best information, knowledge, and belief, that info specified in 438.604 is accurate, complete, and truthful. Certification must be submitted concurrently with information.	Yes	10.09.65.02R	Yes

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.608(a)	Program Integrity.	Program integrity requirements under the contract – administrative and management arrangements or procedures to detect and prevent fraud, waste, and abuse.	Requires MCOs to implement and maintain arrangements or procedures to detect fraud, waste, and abuse. Must include a compliance program; prompt reporting of overpayments identified or recovered (with overpayments due to potential fraud specified) to the state; notification to the state if an enrollee changes residence or dies; notification of when a network provider's circumstances changes and it affects their eligibility to participate in managed care, including provider termination; methods to verify whether services represented as delivered were received by enrollees on a regular basis; written policies related to the False Claims Act and whistleblowers if MCOs receive payments of at least $5 million annually; prompt referral of any potential fraud, waste, or abuse to the State or Medicaid Fraud Control Unit; and suspension of payments to a network provider if the State determines a credible allegation of fraud exists.	Yes	10.09.64.06; 10.09.65.02S; 10.09.65.15	Yes

Table C. Regulations Affecting MCO Contracts On or After July 1, 2017

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.608(c)	Program Integrity.	Program integrity requirements under the contract – disclosures.	State contract must require each MCO and any subcontractors to provide written disclosures of prohibited affiliations and ownership and control. MCOs and subcontractors must report to the state within 60 calendar days when it has identified capitation payments or other payments in excess of amounts in contract.	Yes	10.09.65.02T, 10.09.65.19	Yes
438.608(d)	Program Integrity.	Program integrity requirements under the contract - treatment of recoveries made by the MCO, PIHP, or PAHP of overpayments to providers.	Requires contract to specify policies for MCOs to retain overpayments; the process, timeframes, and documentation to report recovery of overpayments; when the MCO cannot retain some or all overpayments. Does not apply to False Claims Act cases or other investigations. MCOs must have a mechanism for network providers to report they have received an overpayment and to return it within 60 calendar days after the date on which the overpayment was identified, and the reason for the overpayment. MCOs must report annually to the State on overpayment recoveries. States can factor overpayment recoveries into setting actuarially sound cap rates.	Yes	10.09.65.19	Yes

Table D. Regulations Affecting MCO Contracts On or After July 1, 2018

Description	Reg Impact?	Regs Affected	Add to Contract?
CMS will require rates to be sufficient to meet network adequacy and accessibility requirements for review and approval.	No	N/A	No
CMS will require rates to be specific to payments for each rate cell under the contract for review and approval.	No	N/A	No
States can increase or decrease the capitation rate by 1.5 percent without a revised rate certification but they must modify the contract.	No	TBD	TBD
In cases where the MCO contract is terminated or an enrollee is disenrolled for reasons other than ineligibility, the state must arrange for Medicaid services to be provided without delay. State must have a transition of care policy for transition between FFS and an MCO or between MCOs when an enrollee would suffer serious detriment to their health or be at risk of hospitalization or institutionalization. The policy must ensure the enrollee has access to services consistent with what they previously had and is permitted to retain their provider for a period of time if out-of-network for the new MCO, the state or MCO furnishes complete historical utilization data to the new MCO or entity, the new providers can obtain the enrollee's medical records, and any other necessary procedures to ensure continued access to services. MCOs must also implement transition of care policies. The state's policy must be made publicly available, described in the quality strategy, and explained in enrollee materials.	Yes	10.09.63.06; 10.09.66; Ins. Art. 15-140	Yes

Table D. Regulations Affecting MCO Contracts On or After July 1, 2018

Description	Reg Impact?	Regs Affected	Add to Contract?
State must develop time and distance standards for primary care, adult and pediatric; OB/GYN; behavioral health, adult and pediatric; specialists, adult and pediatric; hospital; pharmacy; pediatric dental; and additional provider types as determined by CMS. Standards must include scope of managed care program or scope of contract with MCO. States can have varying standards for provider types based on geographic areas. States must consider the anticipated Medicaid enrollment, expected service utilization, the characteristics and health care needs of the Medicaid populations covered, the numbers and types of network providers, the numbers of providers with closed panels, geographic location of providers, communication with limited English proficient enrollees, accessibility for enrollees with disabilities, and triage lines or screening systems (incl. telemedicine). Any exceptions to a standard must be specified in the MCO contract, based on number of providers practicing in the service area, and states must monitor enrollee access on an ongoing basis and include the findings in the program assessment report to CMS. States must publish these standards on the website and make them available to enrollees at no cost.	Yes	10.09.66.05-1; 10.09.66.06	Yes
Beneficiary support systems are operated by the state and must include choice counseling for all beneficiaries and assistance for enrollees in understanding managed care. Must be accessible by phone, internet, in-person, and via auxiliary aids and services upon request. Choice counseling extends to potential enrollees and enrollees who disenroll from an MCO. Enrollment brokers must meet independence and freedom from conflict of interest standards.	Yes	10.09.63.02	No

Table D. Regulations Affecting MCO Contracts On or After July 1, 2018

Description	Reg Impact?	Regs Affected	Add to Contract?
State must ensure that MCOs maintain and monitor a network of appropriate providers supported by written agreements to provide access to all covered services for all enrollees; provide female enrollees direct access to a women's health specialist for routine and preventive health care; provide for a second opinion from a network provider or arranges for one outside the network at no cost to the enrollee; adequate and timely coverage for services out-of-network if the MCO's provider network cannot cover a service; coordinate care with out-of-network providers and ensure cost to enrollee is no greater than it would be if services were furnished in network; credential network providers; include sufficient family planning providers. Ensure hours of access to providers is comparable to commercial enrollees or Medicaid FFS, make services available 24/7 when medically necessary; have mechanisms to ensure compliance; take corrective action if not in compliance. Must ensure services are provided in a culturally competent manner. Must ensure network providers provide physical access, reasonable accommodations, and accessible equipment for enrollees with physical or mental disabilities.	Yes	10.09.64.07; 10.09.66.05; 10.09.66.05-1; 10.09.66.07; 10.09.66.08; 10.09.67.01	Yes
Through contracts, MCOs must provide assurances to the state with supporting documentation that it has capacity to serve its service areas. Documentation must show the MCO offers an appropriate range of preventive, primary care, and specialty services that are adequate for the anticipated number of enrollees for the service area, and the MCO maintains a provider network sufficient in number, mix, and geographic distribution to meet the needs of anticipated number of enrollees for the service area. MCOs must furnish this information at the time of entering a contract with the state, on an annual basis, and at any time there has been a significant change in the MCO's operations that would affect the adequacy of capacity and services (e.g., changes in services, benefits, service areas, composition of provider network, payments to providers, or enrollment of a new population). The state then must submit assurance of compliance to CMS, including	Yes	10.09.64.07; 10.09.65.15; 10.09.65.17; 10.09.66.05	Yes

Table D. Regulations Affecting MCO Contracts On or After July 1, 2018

Description	Reg Impact?	Regs Affected	Add to Contract?
documentation of an analysis supporting network adequacy for each MCO. CMS has the right to inspect all documentation collected from the MCO.			
State must screen, enroll, and periodically revalidate all network providers of MCOs; this does not require the network providers to participate in fee-for-service.	Yes	10.09.65.02	Yes
Contracts must require all network providers to enroll with the state as Medicaid providers; this does not require the network providers to participate in fee-for-service.	Yes	10.09.65.02	Yes
FFP is available if enrollee encounter data reports comply with HIPAA and are submitted in the format required by MSIS or any successor system; encounter data must be validated for accuracy and completeness before submission to CMS; states must cooperate with CMS to fully comply with MSIS or a successor system; CMS will assess the state's submission and if there are compliance issues, CMS will defer or disallow FFP on all or part of an MCO contract based on the enrollee and specific service type of the noncompliant data.	Yes	10.09.65.15B	Yes

Table E. Regulations Effective No Later Than July 1, 2018

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.340	Quality.	Managed care State quality strategy.	States must draft and implement a written quality strategy that includes at a minimum network adequacy and availability standards, goals for continuous quality improvement for all MCO populations, quality metrics and performance targets, performance improvement projects, annual external independent reviews, the transition of care policy, identification of health disparities (age, race, ethnicity, sex, primary language, and disability status), appropriate use of intermediate sanctions, non-duplication of EQR activities, and definition of "significant change." The strategy must be made available for public comment, to the Maryland Medicaid Advisory Committee (MMAC), and must be reviewed and updated no less than once every 3 years. The review must include an evaluation of the quality	No	N/A	No

Table E. Regulations Effective No Later Than July 1, 2018

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
			strategy from the previous 3 years. Review results must be made available on the website. The strategy must be submitted to CMS for comment and feedback before adopting it in final and when significant changes require updating the strategy.			
438.350	Quality.	External quality review.	Qualified EQRO performs an annual EQR for each MCO, and information for EQR must be obtained from EQR-related activities or from a private accreditation review. Must be conducted according to protocols and results must be made available.	No	10.09.65.03	No
438.354	Quality.	Qualifications of external quality review organizations.	EQRO staff must meet competence and independence requirements.	No	N/A	No
438.356	Quality.	State contract options for external quality review.	Must contract with at least one EQRO, may contract with additional EQROs. EQROs are permitted to subcontract so long as subcontractors meet competence and independence requirements. Must be	No	N/A	No

Table E. Regulations Effective No Later Than July 1, 2018

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
			contracted through an open, competitive procurement process.			
438.358	Quality.	Activities related to external quality review.	Mandatory EQR-related activities: validation of PIPs, validation of MCO performance measures; three-year review to determine MCO compliance with QAPI and other standards; validation of MCO network adequacy annually. Optional EQR-related activities: validation of encounter data; administration or validation of consumer or provider surveys; calculation of performance measures; conduct of PIPs; conduct of focused quality studies; assistance with quality ratings. EQROs may also provide technical assistance to MCOs for EQR-related activities.	Yes	10.09.65.03	Yes

Table E. Regulations Effective No Later Than July 1, 2018

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.360	Quality.	Non-duplication of mandatory activities.	State may use Medicare or private accreditation review to substitute for PIP validation, performance measure validation, and compliance review if the MCO complies with the Medicare or private accrediting organization's standards and they are as stringent as Medicare's standards; the standards are comparable to EQR protocols; the MCO provides the state the reports, findings, and other results. If the state uses information from Medicare or a private accrediting entity, it must furnish all information to the EQRO for analysis and inclusion in the annual technical report. A State must also identify the areas where it has exercised the private accreditation option in the quality strategy.	Yes	10.09.65.03	Yes
438.362	Quality.	Exemption from external quality review.	State may exempt an MCO from EQR if the MCO has a current Medicare contract and a current Medicaid contract, the two contracts cover the same areas of the state, and the Medicaid contract has been in effect for at least 2 consecutive years	Unsure	10.09.65.03	Unsure

Table E. Regulations Effective No Later Than July 1, 2018

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
			before the effective date of the exemption, and during those 2 years, it was performing acceptably in EQR review. If the State exercises this option, the State must obtain the Medicare review findings or the findings from a private national accrediting organization that CMS recognizes for Medicare Advantage Organization deeming.			
438.364	Quality.	External quality review results.	Annual technical report guidelines; must be published on website and provided upon request to interested parties; must safeguard patient identity.	Yes	10.09.65.03	No

Table F. Regulation Affecting MCO Contracts On or After July 1, 2019

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.4(b)(9)	Rate Setting.	Actuarial soundness; CMS review and approval of actuarially sound capitation rates – develop rates so that plan can reasonably achieve an MLR of at least 85 percent.	Rates must be developed such that the MCO would reasonably achieve an MLR standard of at least 85%, so long as the cap rates are adequate for reasonable, appropriate, and attainable non-benefit costs.	No	N/A	No

Table G. Rating Period After CMS Guidance

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.66(e)	MCO Monitoring.	Annual program report.	No later than 180 days after each contract year, the State must submit to CMS a report on each managed care program administered by the State, regardless of authority. Initial report due after CMS issues guidance on content and form. 1115(a) reports will satisfy this requirement if it includes the info specified: financial performance, encounter data reporting, enrollment and service area expansion, modifications and implementation of benefits, grievance/appeal/state fair hearings info, availability/accessibility/network adequacy information, evaluation of quality measures and performance, sanctions or corrective action plans and their results (formal or informal), beneficiary support system activities and performance. Report must be published on the website and provided to MMAC.	No	N/A	No

Table H. Regulation Effective 3 Years From Final Federal Register Notice

CFR Cite	Category	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.334	Quality.	Medicaid managed care quality rating system.	States must adopt the rating system developed by CMS or adopt an alternative rating system and implement it within 3 years of the final Federal Register notice. Ratings must yield info about MCO performance that is comparable to CMS's quality rating system and receive CMS approval. The MCAC must weigh in on modifications or alternatives to the CMS quality rating system and there must be 30 days of public comment before implementing an alternative system or modification. The State must document the public comment process to CMS, and include any policy revisions or modifications made in response to comments received and rationale for comments not accepted. Quality ratings must be determined from data collected annually. Quality ratings must be displayed prominently on the website.	No	N/A	No

Table I. Regulation Effective 1 Year After CMS Issuance of External Quality Review Protocol						
CFR Cite	**Category**	**Title**	**Description**	**Reg Impact?**	**Regs Affected**	**Add to Contract?**
438.358(b)(1)(iv)	Quality; network adequacy.	States must begin conducting the mandatory EQR activity of validation of network adequacy.	Once EQR protocol is issued, states must begin the network adequacy validations annually for each MCO and for Indian populations if they are enrolled in managed care.	Yes	10.09.65.03	Yes

Table J. Regulation Effective No Earlier Than Effective Date of External Quality Review Protocol

CFR Cite	Title	Description	Reg Impact?	Regs Affected	Add to Contract?
438.358(c)(6)	States may begin conducting the optional EQR-related activity of plan rating.	Once the plan rating guidance has been issued, states may use the EQRO for assistance with the plan rating activities from CMS or with an alternative plan rating system.	No	N/A	No