



# Federal Law Governing Medicare Advantage Plans and Medicaid Managed Care Plans

Denise M. Leard, Esq. Brown & Fortunato













- For the first 40 years of its existence, the DME industry was a "fee-for-service" industry. Suppliers billed Medicare and state Medicaid programs directly.
- This has changed. Currently, almost 40% of Medicare beneficiaries are covered by Medicare Advantage Plans ("MAPs") and approximately 70% of Medicaid patients are covered by Medicaid Managed Care Plans ("MMCPs").



- In order to be able to service managed care patients, DME suppliers must:
  - sign contracts with MAPs and MMCPs and
  - adhere to the policies of MAPs and MMCPs.
- This presents challenges for DME suppliers.
  - MAP and MMCP panels may be closed.
  - A MAP/MMCP may enter into a sole service contract with a DME suppler.
  - And the reimbursement may be ridiculously low.
- DME suppliers justifiably want to know what federal oversight there
  is of MAPs and MMCPs and whether such oversight affords
  protections to suppliers.



- Federal statutes and regulations governing Medicare Advantage and Medicaid Managed Care organizations are quite extensive.
- However, only a small portion of the regulations govern the relationship between the organizations and the health care providers that serve the beneficiaries of the plans.
- Most of the regulations aim to protect beneficiaries of the plans and set minimum requirements for coverage, networks, and complex reimbursement mechanisms.



- Generally, the regulations that pertain to providers are aimed at protecting patients' access to care and ensure that the plans have a baseline coverage of medical care and a network with at least a minimum number of providers within a specific geographic region.
- The regulations provide additional protections for beneficiaries by setting requirements for marketing of the plans.
- The federal statutes empower CMS to issue rules regarding the administration of the plans.
- In addition to specific regulation regarding the managed care plans, the plans are also subject to antitrust statutes and federal insurance regulations.







# Federal Law Overview





- Medicare Advantage was created with the passage of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33) which amended the Social Security Act to create the "Medicare+Choice" program, more commonly known as Medicare Advantage or Medicare Part C.
- It has gone through several updates which eventually culminated in the most recent and comprehensive update to the plan passed in the Affordable Care Act in 2010 (Pub. L. 111-152). Medicare Part C allows "eligible individuals to receive benefits through the original Medicare fee-for-service program under parts A and B, or through enrollment in a [Medicare Advantage] plan." 42 U.S.C. § 1395w -21(a)(1).



- The statute sets a baseline of the covered benefits in each MAP.
- "Each [Medicare Advantage] plan shall provide to members through providers benefits under the original Medicare fee-for-service program option." 42 U.S.C. § 1395w – 22(a)(1).
- This requirement is a baseline, but plans are free to provide additional benefits so long as they comply with the cost-sharing limitations set forth in the statute and the regulations issued by CMS.



- Benefits and Covered Services
  - Medicare Advantage regulation is generally aimed at protecting beneficiaries by ensuring that they have the same or better access to services as those covered under traditional Medicare plans, but this does not necessarily mean that it sets up the same level playing field for the providers' access to beneficiaries.
  - The regulations grant the MAPs broad discretion to create a network of providers.
  - MAPs "may select the providers from whom the benefits under the plan are provided" so long as the plan makes the benefits available to all members and the benefits meet the minimum coverage requirements regarding emergency services, maintenance and post-stabilization, and other benefits provided under Medicare Parts A and B.



- Benefits and Covered Services
  - MAPs that operate on a fee-for-service model must demonstrate that the
    organization "has sufficient number and range of health care professionals and
    providers willing to provide services under the terms of the plan." 42 U.S.C. §
    1395w -22(d)(4)
  - The plan can meet this requirement in one of two ways:
    - establish payment rates for covered services that are not less than the payment rates under traditional Medicare; or
    - demonstrate that the plan has contracts or agreements with a sufficient number and range of providers to meet access requirements for each category of care provided under traditional Medicare.



- Benefits and Covered Services
  - The statute specifies that meeting the second requirement should not be construed as "restricting the persons from whom enrollees under such a plan may obtain covered benefits" but the plan may require a higher beneficiary copayment for providers that do not have contracts or agreements to provide covered services under the plan.



- Payments to MAPs
  - MAPs are reimbursed monthly in an amount determined by the model of the plan, whether the plan's bid was above or below the traditional Medicare benchmark, and adjustments based on demographics, geographic variations, etc.
  - Since 2006, MAPs have been required to submit an annual bid that states
    the aggregate monthly amount for the provision of all items and services
    under the plan determined by the average revenue requirements for an
    enrollee with an average risk profile.



- Payments to MAPs
  - CMS exercises authority to oversee and approve the premiums and premium amounts that will be charged to beneficiaries under MAPs.
  - Generally, the statute simply requires plans to adhere to the premium and deductible amounts that shall be determined by the actuarial formulas utilized by CMS.





- Regulations Governing MAPs' Relationships with Providers
  - In addition to the statutory requirements set forth in the Social Security Act, 42 CFR 422 Subpart E governs the relationships between MAPs and health care providers under fee-for-service plans.
  - A Medicare Advantage organization "must have written policies and procedures for the selection and evaluation of providers." 42 CFR § 422.204(a)
  - The policies and procedures must require determination and redetermination on a regular basis that each provider is licensed to operate in the state and accredited or meets standards similar to accreditation that are issued by the organization. Additionally, the policies and procedures must ensure compliance with the regulations that prohibit employment or contracts with individuals excluded from participation in the Medicare program.



- Regulations Governing MAPs' Relationships with Providers
  - MAPs are granted the discretion to "select the practitioners that participate in its plan of provider networks." 42 CFR § 422.205.
  - Plans are prohibited from discriminating against providers solely on the basis of their license or certification, but this prohibition does not preclude the plan from refusing to grant participation to providers in excess of the number "necessary to meet the needs of the plan's enrollees (except for MA private-feefor-service plans, which may not refuse to contract on this basis)." 42 CFR § 422.205(b)



- Regulations Governing MAPs' Relationships with Providers
  - Medicare Advantage Networks must meet minimum requirements for providers within a certain distance and time of the beneficiaries of the plan but may request exceptions to network adequacy criteria in certain circumstances.
  - Network adequacy requirements were most recently updated in August of 2020.







# Federal Law Overview





- At the same time Medicare Advantage was created, the BBA of 1997 granted states the ability to implement a mandatory Medicaid managed care ("MMC") program.
- Regulations of MMC programs are distinct in that the regulations generally set forth minimum requirements that states must enforce as a condition of continued federal funds for the program.
- Generally, the Social Security Act sets forth the requirements for an MMC program that include maintaining at least two programs from which enrollees can choose, minimum coverage benefits for beneficiaries, and processes for enrollment and termination.



- Federal regulations of MMC programs generally mirror the requirements for Medicare Advantage programs in terms of provider relations.
- States must ensure that each MMC organization it contracts with "implements written policies and procedures for selection and retention of network providers." 42 CFR § 438.214.



- MMC organizations may not "discriminate with respect to participation, reimbursement, or indemnification as to any provider who is acting within the scope of the provider's license or certification under applicable State law, solely on the basis of such license or certification." 42 U.S.C. § 1396u 2(b)(7).
- However, like Medicare Advantage, this requirement does not "prohibit an organization from including providers only to the extent necessary to meet the needs of the organization's enrollees or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the organization." 42 U.S.C. § 1396u – 2(b)(7).



- Other Federal Regulations
  - In addition to the regulations specifically targeted at the regulation of managed care plans, other federal regulations that govern insurance apply to these plans. In United States of America v. Aetna Inc., Civ. No. 16-1494 (U.S. Dist. Columbia, Jan. 23, 2017), a federal court enjoined the merger of Aetna and Humana because it found the merger would substantially lessen competition in the Medicare Advantage product market in violation of section 7 of the Clayton Act.
  - MAPs and MMCPs are also subject to the requirements of the Health Insurance Portability and Accountability Act ("HIPAA") and are responsible for HIPAA compliance.







# Minimum Level of Service





- A MAP must offer the "benefits under the original Medicare fee-for-service program option." 42 U.S.C. § 1395w 22(a)(1)(A).
- In addition to the applicable statutes, CMS has codified regulations for MAPs. The regulations state that a MAP must at minimum provide enrollees "basic benefits" and may provide supplemental benefits to enrollees.



- Basic benefits are defined as "all items and services (other than hospice care or, beginning in 2021, coverage for organ acquisitions for kidney transplants) for which benefits are available under Parts A and B of Medicare, including telehealth benefits offered consistent with the requirements at § 422.135." 42 C.F.R. § 422.100(c)(1); 42 U.S.C. § 1395w-22a(1)(B)(i).
- Basic benefits include Part B prescription drugs and durable medical equipment.



- Supplemental benefits consist of both mandatory and optional supplemental benefits. Mandatory supplemental benefits are services not covered by Medicare Part A, Part B or Part D and that an enrollee must purchase as part of a MAP.
- The enrollee is responsible for the costs of such benefits through premiums, cost sharing obligations, or rebates. The enrollee must cover the cost of optional supplemental benefits through an additional premium or cost-sharing. However, the enrollee may not utilize rebate dollars to cover the cost of optional supplemental benefits.



• In addition to supplemental benefits, a MAP may choose to offer Part D benefits. A MAP may not, however, "impose limitations, waiting periods or exclusions from coverage due to pre-existing conditions that are not present in original Medicare." Medicare Managed Care Manual Ch. 4, § 10.2.



- While a MAP must provide all medically necessary Part A and Part B covered items and services, there are limited exceptions:
  - Hospice Original Medicare will cover the cost of hospice services if the enrollee has elected hospice while enrolled in a MAP.
  - <u>Clinical Trials</u> An enrollee's costs of routine services are covered by original Medicare. The MAP will pay an enrollee the difference between original Medicare's cost-sharing obligation for qualifying clinical trial items and services and the MAP's "in-network cost-sharing for the same category of items and services."
  - Inpatient Hospital Stays If an enrollee's MAP coverage takes effect after an inpatient stay begins, but prior to discharge from the stay, then original Medicare will cover the costs of the inpatient stay while the beneficiary is responsible for the cost-share.



- A MAP must also provide payment for any of the following services, regardless of whether the provider or supplier maintains a contract with the MA organization:
  - Ambulance services.
  - Emergency and urgently needed services.
  - Maintenance and post-stabilization care services.
  - Renal dialysis services provided while the enrollee was temporarily outside the plan's service area.
  - Services for which coverage has been denied by the MAP and found to be services the enrollee was entitled to have furnished, or paid for, by the MAP.



- Section 1932 of the Social Security Act provides State Medicaid programs the option to utilize Medicaid Managed Care Organizations ("MMCO") to assist with administering the state's Medicaid plan.
- A state may require Medicaid beneficiaries to enroll in the MMCO administered MMCP.
- A contracted MMCO must provide MMCP enrollees the same services that would be available to the same individual if he or she were enrolled in the state's Medicaid plan.
- The minimum services required in a state Medicaid plan are set forth in 42 C.F.R. § 440.210 (required services for the categorically needy) and 42 C.F.R. § 440.220 (required services for the medically needy).







# Access to Care Requirements





- Federal law requires MAPs to provide enrollees with coverage of all services that are covered by Medicare Parts A and B ("traditional Medicare").
- Additional benefits may be offered beyond those covered by traditional Medicare.
- Additional benefits may be
  - a reduction in the premiums, deductibles and coinsurance payments ordinarily required or
  - health care services not covered by traditional Medicare such as dental and vision care or certain preventative services.
- Many MAPs also include Part D prescription drug coverage.



- A Medicare Advantage Organization ("MAO") that offers an MAP may be specific as to what network providers enrollees may use, but to do so they must ensure that all covered services are available and covered under the MAP.
- There are 10 requirements that must met by the MAP in establishing a provider network.
  - The MAP must maintain and monitor a network of appropriate providers that is
    - supported by written agreements and
    - sufficient to provide adequate access to covered services to meet the needs of the population served.
  - Methods other than written agreements are allowed to be used but they must be pre-approved by CMS.



- The MAP must establish a panel of primary care providers ("PCPs") from which an enrollee may select a PCP. In the event an enrollee is required to obtain a referral before receiving services from a specialist, the MAP must either assign a PCP for purposes of making the needed referral or make other arrangements to ensure access to medically necessary medical care.
- The MAP must provide or arrange for necessary specialty care. In the event the network providers are unavailable or inadequate to meet an enrollee's medical needs, the MAP must arrange for specialty care outside of the MAP provider network.
- If the MAP seeks to expand the service area of the MAP, it must demonstrate
  that the number and type of providers available to plan enrollees are sufficient
  to meet projected needs of the population to be served.
- The MAO must demonstrate to CMS that the providers in the MAP are credentialed.



- The MAP must have written standards that
  - establish the timeliness of access to care and
  - require member services that meet or exceed the standards established by CMS.
- The MAP must continuously monitor the timely access to care within its provider network and take corrective action as necessary. 42 C.F.R. § 422.112(a)(6)(i). The MAP must have policies and procedures that
  - allow for individual medical necessity determinations and
  - have provider consideration of beneficiary input into the provider's proposed treatment.
- A MAP is required to employ written standards for timeliness of access to care and member services that meet or exceed the standards as may be established by CMS. The MAP must ensure that, when medically necessary, services are available 24 hours a day, 7 days a week.



- The MAP must ensure that
  - its providers have convenient hours of operation for the population served,
  - it does not discriminate against Medicare enrollees and
  - the plan services must be available 24 hours a day, 7 days a week, when medically necessary.
- The MAP must ensure that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds.
- The MAP must provide coverage for ambulance services, emergency and urgently needed services.



- The MAP that meets Medicare access and availability requirements through direct contracting with network providers must do so consistently with the prevailing community pattern of health care delivery in the areas where the network is being offered.
- The network adequacy standards are established in 42 C.F.R. § 422.116. CMS only requires an attestation by the MAP regarding compliance with the network adequacy standards established by CMS. The MAP must meet the maximum time and distance standards and contract with a specific minimum number of each provider and facility-specialty type.



- Each Medicaid MCO must provide assurances that
  - its plan offers an appropriate range of services and access to both preventative and primary care for the population that is expected to enroll in each service area and
  - the MAP will maintain a distribution of providers that are of a sufficient number, type, and location.
- This requirement varies state by state. The standards for access to care must be available within reasonable timeframes and in a manner that ensures continuity of care and adequate primary care and specialized services capacity.



- State Medicaid programs use three main types of managed care delivery system:
  - comprehensive risk-based managed care,
  - primary care case management, and
  - limited-benefit plans. In a comprehensive risk-based managed care arrangement, states contract with MCOs to cover all or most Medicaidcovered services for their Medicaid enrollees.
- In a primary care case management program, each enrollee has a designated PCP who is paid a monthly case management fee to be responsible for managing and coordinating the enrollee's basic medical care.



- In a limited-benefit plan, a state contracts with the plan to manage specific benefits, such as inpatient mental health or substance abuse benefits, nonemergency transport, oral health, or disease management.
- The states are required to develop and enforce network adequacy standards in accordance with federal regulations.
- The network standards must include all of the geographic areas covered by the MMCP. It is possible for the contract between the state and the MMCP to have varying standards for the same provider type based on the geographic area that is covered.



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- Any exceptions granted by the state to the MMCP is required to be specified in the contract and based on the number of providers practicing in that specialty in the MMCP service area.
- The basic rule for availability of service is that the state must ensure that all services covered by the MMCP are available and accessible to enrollees in a timely manner.
- Each state establishes its own standards. The state must ensure the MMCP maintains and monitors a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to all services covered under the contract with enrollees.



- If a provider network is unable to provide necessary services, covered under the contract, to a particular enrollee, the MMCP must adequately and timely cover these services out of network for the enrollee, for as long as the MMCP's network is unable to provide them.
- States are allowed to set appropriate and meaningful quantitative standards for their programs. The state must also ensure that the MMCP will coordinate with out-of-network providers for payment and ensure that the cost to the enrollees is no greater than it would be if the services were furnished within the network.



• The MMCP is required to demonstrate that its network providers are credentialed. The state must ensure that each MMCP implements written policies and procedures for selection and retention of network providers and that the policies and procedures meet Federal guidelines. MMCPs must follow a documented process for credentialing and recredentialing of network providers.





 Each MMCP must provide timely access, cultural considerations, and accessibility considerations. Timely access requirements include meeting the state standards for timely access to care and services while considering the urgency of the need for services. The hours of operation for the network providers can be no less than the hours of operation offered to commercial enrollees or comparable to Medicaid. The MMCPs must make services included in the contract available 24 hours a day, 7 days a week when medically necessary. The MMCPs need to enact mechanisms to ensure compliance by network providers and monitor them regularly to ensure compliance. If the network provider fails to comply with the requirements, then the MMCP is required to take corrective action.









# Rights of a DME Supplier





### Introduction

- There are no federal laws that directly provide relief to a DME supplier when the DME supplier believes that the MAP or MMCP is violating its contract with the supplier.
- Medicare provides appeal rights, that a supplier may request, when a MAP makes certain determinations that affect an enrollee's coverage or benefits.
- Federal Medicaid laws require that the state develop a plan for its managed Medicaid program.



### Introduction

- It appears that a contract dispute between a DME supplier and MAP will not implicate Medicare laws unless the contract violation pertains to a Medicare requirement the MAP is obligated to meet.
- Similarly, it appears that a contract dispute between a DME supplier and MMCP will not implicate federal Medicaid laws unless the contract violation pertains to a requirement that the state is required to meet as a part of offering a managed Medicaid program.
- There is not a set regulatory process for the DME supplier to pursue such claims.











- There are no Medicare laws that directly provide a DME supplier with remedies when a MAP violates its contract with the DME supplier. Medicare requires the following provisions to be included in a contract between a MAP and supplier:
  - Contracting providers must agree to safeguard beneficiary privacy and confidentiality and assure accuracy of beneficiary health records.
  - Contracts must specify a prompt payment requirement, the terms and conditions of which are developed and agreed to by the MAP and its contracted providers and suppliers.
  - Contracts must hold Medicare beneficiaries harmless for payment of fees that are the legal obligation of the MAP to fulfill.



- Contracts must contain accountability provisions specifying:
  - that first tier and downstream entities must comply with Medicare laws, regulations, and CMS instructions, and agree to audits and inspection by CMS and/or its designees and to cooperate, assist, and provide information as requested, and maintain records for a minimum of 10 years;
  - that the MAP oversees and is accountable to CMS for any functions and responsibilities described in the MAP regulations; and
  - that MAPs that choose to delegate functions must adhere to the delegation requirements - including all provider contract requirements in these delegation requirements - described in the MAP regulations.



 Contracts must specify that providers agree to comply with the MAP's policies and procedures





- Note that the MAP retains discretion in determining many of the terms of the required contract provisions. For example, while the contract must contain a "prompt payment requirement," it is up to the MAP and supplier to agree on the terms and conditions of the requirement.
- Federal statutes and regulations are more protective of MAP enrollees.
- CMS is not allowed to approve a MAP if CMS determines that "the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA [i.e., Medicare Advantage] eligible individuals with the organization." 42 U.S.C. § 1395w -22(b)(1).
- 42 U.S.C. § 1395w-22(d) requires the MAP to provide certain levels of access to services, including "immediately required" services provided out-of-network.



- 42 U.S.C. § 1395w-22(f) requires that the MAP have a grievance process for enrollees.
- 42 C.F.R. § 422.566(a) provides that "Each MA organization must have a procedure for making timely organization determinations regarding the benefits an enrollee is entitled to receive under an MA plan ... "
- 42 C.F.R. § 422566(b) defines "organization determinations" to include the following:
  - Actions that are organization determinations. An organization
    determination is any determination made by an MA organization with respect
    to any of the following:



- 1. Payment for temporarily out of the area renal dialysis services, emergency services, post-stabilization care, or urgently needed services.
- 2. Payment for any other health services furnished by a provider other than the MA organization that the enrollee believes -
  - Are covered under Medicare; or
  - ii. If not covered under Medicare, should have been furnished, arranged for, or reimbursed by the MA organization.
- 3. The MA organization's refusal to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the MA organization.



- 4. Reduction, or premature discontinuation, of a previously authorized ongoing course of treatment.
- 5. Failure of the MA organization to approve, furnish, arrange for, or provide payment for health care services in a timely manner, or to provide the enrollee with timely notice of an adverse determination, such that a delay would adversely affect the health of the enrollee.



- 42 C.F.R. § 422.566(c) provides that "Any provider that furnishes, or intends to furnish, services to the enrollee" may request an organization determination. A party unhappy with the outcome of an organization determination may request that the determination be reconsidered within 60 days from the date of notice of the organization determination. 42 U.S.C. § 422.578.
- A party unhappy with the reconsideration (excluding the MAP) may file a request for a hearing within 60 days of receipt of the adverse notice of reconsideration determination. 42 C.F.R. § 422.596.
- A party unhappy with the outcome of the ALJ hearing may request a review by the Medicare Appeals Council within 60 days. 42 U.S.C. § 422.608.
- A party unhappy with the decision of the Medicare Appeals Council may request judicial review within 60 days provided the amount in controversy is at least \$1,760 (for 2021 and 2022). 42 C.F.R. 422.612.











- There are no federal Medicaid laws that directly provide a DME supplier with remedies when an MMCP violates its contract with a DME supplier.
- 42 C.F.R. § 438.66 requires the state to monitor its managed care programs:
  - a. General requirement. The State agency must have in effect a monitoring system for all managed care programs.
  - b. The State's system must address all aspects of the managed care program, including the performance of each MCO, PIHP, PAHP, and PCCM entity (if applicable) in at least the following areas:
    - Administration and management.
    - Appeal and grievance systems.
    - 3. Claims management.
    - 4. Enrollee materials and customer services, including the activities of the beneficiary support system.



- Administration and management.
- 2. Appeal and grievance systems.
- 3. Claims management.
- 4. Enrollee materials and customer services, including the activities of the beneficiary support system.
- 5. Finance, including medical loss ratio reporting.
- 6. Information systems, including encounter data reporting.
- 7. Marketing.
- Medical management, including utilization management and case management.
- 9. Program integrity.
- 10. Provider network management, including provider directory standards.





- 11. Availability and accessibility of services, including network adequacy standards.
- 12. Quality improvement.
- 13. Areas related to the delivery of LTSS not otherwise included in paragraphs (b)(1) through (12) of this section as applicable to the managed care program.
- 14. All other provisions of the contract, as appropriate.





- In addition, the state must collect data from its monitoring activities to improve its managed care program, including "provider complaint and appeal logs." 42 C.F.R. § 438.66(c)
- A DME supplier that believes an MMCP is not meeting certain standards (e.g., network adequacy standards, medical management) may need to complain through the state. 42 C.F.R. § 438.68(c) requires states to consider certain network adequacy standards for certain providers, including long-term services and supports ("LTSS") provider types, that could include DME suppliers:



- States developing network adequacy standards consistent with paragraph (b)(1) [certain providers, such as certain physician specialists] of this section must consider, at a minimum, the following elements:
  - The anticipated Medicaid enrollment.
  - ii. The expected utilization of services.
  - iii. The characteristics and health care needs of specific Medicaid populations covered in the MCO, PIHP, and PAHP contract.
  - iv. The numbers and types (in terms of training, experience, and specialization) of network providers required to furnish the contracted Medicaid services.
  - The numbers of network providers who are not accepting new Medicaid patients.



- vi. The geographic location of network providers and Medicaid enrollees, considering distance, travel time, the means of transportation ordinarily used by Medicaid enrollees.
- vii. The ability of network providers to communicate with limited English proficient enrollees in their preferred language.
- viii. The ability of network providers to ensure physical access, reasonable accommodations, culturally competent communications, and accessible equipment for Medicaid enrollees with physical or mental disabilities.
- ix. The availability of triage lines or screening systems, as well as the use of telemedicine, e-visits, and/or other evolving and innovative technological solutions.
- As the regulations require the state to develop a plan to address these elements, a DME supplier would need to look to the state to determine whether an MMCP is in violation of the state's plan.







# Questions?









# Thank you

Denise M. Leard, Esq. dleard@bf-law.com | 806-345-6318





