RIGHTS OF A DME SUPPLIER UNDER A MEDICARE ADVANTAGE PLAN AND A MEDICAID MANAGED CARE PLAN

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This White Paper discusses the federal laws that address (i) the steps a DME supplier can take when it concludes that a Medicare Advantage Plan ("MAP") is taking steps that violate the contract between the supplier and the MAP, or steps that are otherwise unfair/detrimental to the DME supplier and/or its patients; and (ii) the steps a DME supplier can take when it concludes that an Managed Medicaid Care Plan ("MMCP") is taking steps that violate the contract between the supplier and the MMCP, or steps that are otherwise unfair/detrimental to the DME supplier and/or its patients.

Short Answer

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. 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.

Medicare

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. Such provision will apply but will not be limited to insolvency of the MAP, contract breach, and provider billing.
- Contracts must contain accountability provisions specifying:
 - o 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;
 - o 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. 1

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. Under 42 U.S.C. § 1395w–22(b)(1), a MAP "may not deny, limit, or condition the coverage or provision of benefits ... for individuals permitted to be enrolled with the organization ... based on any health status—related factor." 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."²

The Social Security Act at 42 U.S.C. § 1395w-22(d) also requires the MAP to provide certain levels of access to services, including "immediately required" services provided out-of-network:

- (1) IN GENERAL.—A Medicare+Choice organization offering a Medicare+Choice plan may select the providers from whom the benefits under the plan are provided so long as—
 - (A) the organization makes such benefits available and accessible to each individual electing the plan within the plan service area with reasonable promptness and in a manner which assures continuity in the provision of benefits;
 - (B) when medically necessary the organization makes such benefits available and accessible 24 hours a day and 7 days a week;
 - (C) the plan provides for reimbursement with respect to services which are covered under subparagraphs (A) and (B) and which are provided to such an individual other than through the organization, if—
 - (i) the services were not emergency services (...), but (I) the services were medically necessary and immediately required because of an unforeseen illness, injury, or condition, and (II) it was not reasonable given the circumstances to obtain the services through the organization,

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¹ Centers for Medicare & Medicaid Services, Internet-Only Manual 100-16, Ch. 11, § 100.4.

² 42 U.S.C. § 1395w-22(b)(1). Section 201(b) of Public Law 108-173 (stating that "any reference to 'Medicare+Choice' is deemed a reference to 'Medicare Advantage' and 'MA."").

- (ii) the services were renal dialysis services and were provided other than through the organization because the individual was temporarily out of the plan's service area, or
- (iii) the services are maintenance care or post–stabilization care covered under the guidelines established under paragraph (2);
- (D) the organization provides access to appropriate providers, including credentialed specialists, for medically necessary treatment and services; and
- (E) coverage is provided for emergency services (...) without regard to prior authorization or the emergency care provider's contractual relationship with the organization.

The Social Security Act, at 42 U.S.C. § 1395w-22(f) requires that the MAP have a grievance process for enrollees:

(F) GRIEVANCE MECHANISM.—Each Medicare+Choice organization must provide meaningful procedures for hearing and resolving grievances between the organization (including any entity or individual through which the organization provides health care services) and enrollees with Medicare+Choice plans of the organization under this part.

42 C.F.R. § 422.566(a) further provides that--

Each MA organization must have a procedure for making timely organization determinations (in accordance with the requirements of this subpart) regarding the benefits an enrollee is entitled to receive under an MA plan, including basic benefits as described under § 422.100(c)(1) and mandatory and optional supplemental benefits as described under § 422.102, and the amount, if any, that the enrollee is required to pay for a health service.

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 -
 - (i) 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.³ 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.⁴ A party unhappy with the outcome of the ALJ hearing may request a review by the Medicare Appeals Council within 60 days.⁵ 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).⁶

Medicaid

There are no federal Medicaid laws that directly provide a DME supplier with remedies when an MMCP violates its contract with a DME supplier. States may implement managed Medicaid programs using managed care organizations under three federal statutes. Section 1932(a) of the Social Security Act, 42 U.S.C. § 1396u-2(a), provides:

- (1) Use of Medicaid managed care organizations and primary care case managers.—
 - (A) IN GENERAL.—Subject to the succeeding provisions of this section, and notwithstanding paragraph (1), (10)(B), or (23)(A) of section 1902(a), a State—

³ 42 C.F.R. § 422.578; See also, 42 C.F.R. § 422.582(b) (providing the "timeframe for filing a request").

⁴ 42 C.F.R. § 422.596; See also, 42 C.F.R. § 422.602(b) (indicating "when to file a request").

⁵ 42 C.F.R. § 422.608.

⁶ 42 C.F.R. § 422.612; *See also*, Centers for Medicare & Medicaid Services, *Appeals Level 5: Federal district court judicial review*, available online at https://www.medicare.gov/claims-appeals/file-an-appeal/appeals-level-5-federal-district-court-judicial-review.

- (i) may require an individual who is eligible for medical assistance under the State plan under this title to enroll with a managed care entity as a condition of receiving such assistance (and, with respect to assistance furnished by or under arrangements with such entity, to receive such assistance through the entity), if—
 - (I) the entity and the contract with the State meet the applicable requirements of this section and section 1903(m) or section 1905(t), and
 - (II) the requirements described in the succeeding paragraphs of this subsection are met; and
- (ii) may restrict the number of provider agreements with managed care entities under the State plan if such restriction does not substantially impair access to services.⁷

An MMCP may not discriminate against an enrollee based on health status and must cover certain services that are "immediately required," as Section 1903(m) provides in relevant part:

- (v) such contract provides that in the entity's enrollment, reenrollment, or disenrollment of individuals who are eligible for benefits under this title and eligible to enroll, reenroll, or disenroll with the entity pursuant to the contract, the entity will not discriminate among such individuals on the basis of their health status or requirements for health care services;
- (vi) ...
- (vii) such contract provides that, in the case of medically necessary services which were provided (I) to an individual enrolled with the entity under the contract and entitled to benefits with respect to such services under the State's plan and (II) other than through the organization because the services were immediately required due to an unforeseen illness, injury, or condition, either the entity or the State provides for reimbursement with respect to those services,

Section 1915 of the Social Security Act, 42 U.S.C. § 1396n allows a state to offer a managed Medicaid program under certain "waivers":

(a) A State shall not be deemed to be out of compliance ... solely by reason of the fact that the State (or any political subdivision thereof)—

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⁷ Section 1903(m) of the Social Security Act requires "Medicaid managed care organization" to (i) make services it provides to Medicaid enrollees accessible to the same extent as such services are made accessible to non-Medicaid enrollees, and (ii) to make adequate provision against the risk of insolvency. Section 1905(t) of the Social Security Act pertains to "primary care case managers."

- (1) has entered into—
 - (A) a contract with an organization which has agreed to provide care and services in addition to those offered under the State plan to individuals eligible for medical assistance who reside in the geographic area served by such organization and who elect to obtain such care and services from such organization, or by reason of the fact that the plan provides for payment for rural health clinic services only if those services are provided by a rural health clinic; or
 - (B) arrangements through a competitive bidding process or otherwise for the purchase of laboratory services ... or medical devices if the Secretary has found that—
 - (i) adequate services or devices will be available under such arrangements...
- (b) The Secretary, to the extent he finds it to be cost-effective and efficient and not inconsistent with the purposes of this title, may waive such requirements of section 1902 (other than subsection (s)) (other than sections 1902(a)(15), 1902(bb), and 1902(a)(10)(A) insofar as it requires provision of the care and services described in section 1905(a)(2)(C)) as may be necessary for a State—
 - (1) to implement a primary care case-management system or a specialty physician services arrangement which restricts the provider from (or through) whom an individual (eligible for medical assistance under this title) can obtain medical care services (other than in emergency circumstances), if such restriction does not substantially impair access to such services of adequate quality where medically necessary....
- (c)(1) The Secretary may by waiver provide that a State plan approved under this title may include as "medical assistance" under such plan payment for part or all of the cost of home or community-based services (other than room and board) approved by the Secretary which are provided pursuant to a written plan of care to individuals with respect to whom there has been a determination that but for the provision of such services the individuals would require the level of care provided in a hospital or a nursing facility or intermediate care facility for the mentally retarded the cost of which could be reimbursed under the State plan. For purposes of this subsection, the term "room and board" shall not include an amount established under a method determined by the State to reflect the portion of costs of rent and food attributable to an unrelated personal caregiver who is residing in the same household with an individual who, but for the assistance of such caregiver, would require admission to a hospital, nursing facility, or intermediate care facility for the mentally retarded.

Managed Medicaid Plans under section 1915(b) are sometimes referred to as "freedom-of-choice" waivers, and managed Medicaid plans under section 1915(c) are often referred to as "home and community-based care" waivers.

Managed Medicaid plans must conform with 42 C.F.R. § 438.50 unless the plan is (i) part of a demonstration project under section 1115(c) of the Social Security Act, or (ii) granted under a Section 1915(b) of the Social Security Act. 8 42 C.F.R. § 438.50(c) requires that:

The plan must provide assurances that the State meets applicable requirements of the following statute and regulations:

- (1) Section 1903(m) of the Act, for MCOs and MCO contracts.
- (2) Section 1905(t) of the Act, for PCCMs and PCCM or PCCM entity contracts.
- (3) Section 1932(a)(1)(A) of the Act, for the State's option to limit freedom of choice by requiring beneficiaries to receive their benefits through managed care entities.
- (4) This part, for MCOs, PCCMs, and PCCM entities.
- (5) Part 434 of this chapter [containing requirements for contracts and subcontracts], for all contracts.
- (6) Section 438.4, for payments under any risk contracts, and § 447.362 of this chapter for payments under any nonrisk contracts.

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:
 - (1) 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.

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⁸ 42 C.F.R. § 438.50(a).

- (5) Finance, including medical loss ratio reporting.
- (6) Information systems, including encounter data reporting.
- (7) Marketing.
- (8) 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." 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:

- (1) 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:
 - (i) 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.

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⁹ 42 C.F.R. § 438.66(c).

- (v) 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.
- (2) States developing standards consistent with paragraph (b)(2) [for LTSS providers] of this section must consider the following:
 - (i) All elements in paragraphs (c)(1)(i) through (ix) of this section.
 - (ii) Elements that would support an enrollee's choice of provider.
 - (iii) Strategies that would ensure the health and welfare of the enrollee and support community integration of the enrollee.
 - (iv) Other considerations that are in the best interest of the enrollees that need LTSS. 10

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 or causing the state to be in violation of its obligations under the regulations.

THIS WHITE PAPER DOES NOT CONSTITUTE LEGAL ADVICE. THIS WHITE PAPER WAS PREPARED ON A SPECIFIC DATE. THE LAW MAY HAVE CHANGED SINCE THIS WHITE PAPER WAS WRITTEN. BEFORE ACTING ON THE ISSUES DISCUSSED IN THIS WHITE PAPER, IT IS IMPORTANT THAT THE READER OBTAIN ADVICE FROM A HEALTH CARE ATTORNEY.

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¹⁰ 42 C.F.R. § 438.2 (defining "Long-term services and supports" as "LTSS").