
Medicare Managed Care Manual

Department of Health and
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal No 7

Date: MARCH 20, 2002

CHAPTERS	REVISED SECTIONS	NEW SECTIONS	DELETED SECTIONS
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**NEW/REVISED MATERIAL--EFFECTIVE/IMPLEMENTATION DATE: Not
Applicable**

This is the initial issuance of Chapter 10 of the Medicare Managed Care Manual, Organization Compliance with State Law and Pre-emption by Federal Law. Chapter 10 addresses State licensure requirements, M+C certification by a State agency, and preemption of State law by Federal law.

These instructions should be implemented within your current operating budget.

NOTE: Normally red italicized font identifies new material. However, because this chapter is new, normal text font is used for the initial release.

Medicare Managed Care Manual

Chapter 10 - Organization Compliance with State Law and Preemption by Federal Law

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10 - CFR §422.400 State Licensure and Scope of Licensure

(Rev. 7, 03-20-02)

Federal regulations at [42 CFR §422.400](#) require each M+C organization (with the exception of Federally-waivered provider-sponsored organizations as described in [42 CFR §422.370](#)) to be licensed or otherwise authorized to operate under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers one or more M+C plans. The intent of this requirement is to ensure that each organization offering an M+C plan has the necessary State authority to do so, and it ensures that each organization will meet State solvency standards.

Each M+C organization must have two basic types of State authority. First, each M+C organization must be authorized by the appropriate State regulatory agencies to operate as a risk-bearing entity offering health insurance or health benefits coverage. Examples of this authority include licenses to offer indemnity insurance, HMO, or Provider Sponsored Organization (PSO) coverage. A certificate of authority or some other type of certification to operate as a risk-bearing entity offering health insurance or health benefits may also be acceptable, if that is all that is required by the appropriate State regulatory agencies. Second, the M+CO must have authority to offer the type of M+C plan the organization wishes to offer (e.g., coordinated care plan, PPO, private fee-for-service, or Medicare Savings Accounts); in other words, the product must be within the scope of its authority to operate as a risk-bearing entity. For example, an organization that is State licensed as an indemnity insurer may not have the necessary State authority to offer an M+C coordinated care plan because operating a health care provider network is not within the scope of an indemnity license. In this case, the State may require the organization to obtain an HMO license in order to offer a M+C coordinated care plan. Similarly, a State may require an organization that is a licensed HMO to obtain separate licensure as an indemnity insurer in order to offer an M+C point-of-service plan. Some organizations may have a limited licensure or certification status allowing them to function as risk-bearing entities in certain markets (e.g., Medicaid) or for certain services only (e.g., a prepaid dental plan). For such organizations, the State licensing authority or authorities responsible for licensing comprehensive prepaid plans in the commercial

marketplace, or for other Medicare risk plans, would be the appropriate authority for determining whether the offering of a M+C plan is within the scope of the organization's existing license or authority to operate.

20 - M+C State Certification Form

(Rev. 7, 03-20-02)

To establish the licensure status of organizations, and in particular to determine compliance with the scope of licensure requirement, CMS requires certification from the appropriate State regulatory agency that both the licensure and scope of licensure requirements are met. The M+C State Certification Form is included in the M+C application for this purpose. CMS also requires organizations licensed to undertake non-commercial business (e.g., Medicaid) and organizations not licensed to undertake commercial business to obtain an additional certification from the appropriate State regulatory agency that they meet appropriate solvency standards.

30 - Specific and General Federal Preemption of State Law

(Rev. 7, 03-20-02)

[Section 1856](#) (b)(3) of the Social Security Act (“the Act”) provides for the Federal preemption of State laws related to the Medicare+Choice program. Preemption is a judicial doctrine asserting the supremacy of Federal legislation over State legislation of the same subject matter. The effect of preemption is to deprive a State of jurisdiction over matters on which Congress has legislated. Section 1856(b)(3)(A) of the Act provides for a Federal preemption of State laws, regulations, and standards affecting any M+C standard if the State provisions are inconsistent with Federal standards (a policy referred to below as general preemption). There is also a specific preemption of State laws (§1856(b)(3)(B) of the Social Security Act) in four areas where Federal standards “preempt the field”; that is, regardless of whether State laws are inconsistent with Federal standards, Federal standards will govern in these four areas. The two types of preemption apply to Medicare lines of business. Neither type of preemption - general preemption or specific preemption - apply to non-M+C lines of business. Arrangements not subject to preemption include those falling outside the scope of the M+C contract, but still relating to Medicare beneficiaries (such as arrangements for benefits connected with a particular employer group or union through a separate arrangement between the M+C offeror and the employer or union).

40 - Specific Preemption

(Rev. 7, 03-20-02)

Following is a discussion of each type of preemption, its effect and practical application. Federal law preempts State law in four specific areas (per [§1856\(b\)\(3\)\(B\)](#) of the Social Security Act):

1. Benefits (including cost-sharing requirements);
2. Inclusion and treatment of providers;
3. Coverage determinations (including related appeals and grievances); and
4. Marketing materials, summaries and schedules of benefits regarding an M+C plan.

With regard to M+C organizations, States need to determine the provisions of State law which do not apply, or no longer apply, to the M+C products of M+COs doing business in the State.

Prior to the passage of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), CMS had limited the specific benefit preemption to benefits (items and services) **per se**, but had not extended the preemption to cost-sharing standards imposed by a State with respect to benefits. Section 614 of BIPA, clearly changes that policy by stating that “benefit mandates, including cost-sharing requirements” are specifically preempted. Accordingly, State cost-sharing requirements relating to benefits offered by an M+C plan are specifically preempted.

CMS has adopted a narrow interpretation of the specific preemption rules regarding “coverage determinations (including related appeals and grievances).” CMS interprets this to apply only to “organization determinations” (as defined in 42 CFR §422.566(b)) that are subject to the Medicare appeals process.

CMS classifies a request for a review of a coverage determination, or request for payment of a claim for what the enrollee believes to be a covered service, as an appeal. CMS classifies a complaint relating to issues such as difficulty in scheduling an appointment or in length of waiting room time as a grievance. A Medicare beneficiary may file a “grievance” asking for payment of a claim for services received from an out-of-plan provider. However, this type of grievance would be classified by CMS as an appeal that is exclusively subject to the Medicare appeals process.

The Medicare appeals process is the exclusive avenue for settlement of a dispute over whether an item or service is covered under the Medicare + Choice contract (including as a supplemental service or additional benefit not covered under traditional Medicare), but only with respect to the “coverage” issue (whether there is coverage and what the

beneficiary liability is for a covered service). The Medicare appeals process is **not** the exclusive process for all matters that may be **related** to the issue under dispute. CMS specifies that State tort and contract law may still apply to such disputes.

While review of coverage determination must go through the M+C appeals process, a beneficiary may also have a valid claim under State tort or contract law. Thus, States may investigate consumer complaints to determine if the complaint falls outside of the specific preemption area, and is therefore subject to State jurisdiction. For example, there can be recourse under State law for a claim of malpractice for having delayed the provision of a service that was determined, through the Medicare appeals process, to be covered under the contract. Or there can be a claim under contract law based on a provision in a member contract for service which are not covered services under the M+ C contract between the Federal government and the M+C organization.

Another change brought by BIPA is the specific preemption of State requirements relating to marketing materials, summaries, and schedules of benefits regarding an M+C plan. This includes requirements relating to the Evidence of Coverage, Summary of Benefits, as well as all other marketing materials. States no longer can require M+C organizations to submit M+C marketing materials for review and approval. However, CMS encourages M+C organizations to continue to share marketing materials with the appropriate State officials.

The following table illustrates examples of specific preemption.

SPECIFICALLY PREEMPTED
<p>State Standards On:</p> <ul style="list-style-type: none">• Direct access to provider requirements, whether in-plan or out-of-plan• Benefit mandates including cost sharing• Appeals and grievances with respect to M+C coverage determinations• Inclusion and treatment of providers (such as "any willing provider" laws; requirement of inclusion of specific types of providers as network providers)• Requirements relating to content, design and/or review of marketing materials

50 - General Preemption

(Rev. 7, 03-20-02)

Generally, except in the four areas of specific preemption, M+C organizations must comply with **all** State laws and standards applicable to insurers or health plans, as well as **all** Federal laws and standards applicable to M+C organizations and plans. However, insurers and health plans are not required to adhere to State laws and standards, with respect to their Medicare operations, to the extent those laws or standards are inconsistent with Federal laws and standards.

It is CMS's policy to consider a State law or standard inconsistent with Federal law **only** if adherence to the State law or standards prevents the health plan or insurer from complying with a Federal standard. State laws or standards that are more stringent than Federal standards are not necessarily inconsistent with Federal standards and might not be preempted by Federal law. For example, the Federal prompt payment of claims provision requires payment within 30 days, and payment of interest at a variable rate determined by the U.S. Treasury for claims paid after 30 days. A State law pertaining to prompt payment of claims and payment of interest which requires an organization to pay an interest rate of 15 percent on claims reimbursed later than 15 days after the date of service, would not necessarily be preempted by the Federal prompt payment provision (since complying with the State standard does not prevent the M+C Organization from also meeting the Federal standard). However, a State law requiring payment of 5 percent interest on claims paid later than 35 days would be preempted under general preemption because the organization would be out of compliance with Federal law for claims paid after 30 days. Further, a State requirement of a 15 percent interest rate after 40 days would not be preempted, assuming the U.S. Treasury rate is less than 15 percent. In that case, the U.S. Treasury rate would apply for claims paid on days 31-40; the State rate could apply after 40 days.

In summary, with regard to general preemption, State standards are preempted only to the extent that they conflict with Federal standards. M+C Organizations otherwise must meet both Federal and State standards. Examples of State functions and standards that could potentially be affected by general preemption are listed below.

<p style="text-align: center;">STANDARDS AND PROCEDURES SUBJECT TO GENERAL PREEMPTION ONLY IF STATE LAW IS INCONSISTENT WITH M+C STANDARDS</p>

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| <ul style="list-style-type: none">• Market conduct examinations• Timely payment of claims standards• Enforcement actions• Unfair claim settlement standards governing the process for determination of benefits as opposed to the benefits themselves• Investigation of consumer complaints |
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- Utilization Review programs and standards
- Quality Assurance programs
- Adequacy of provider network
- Filing and review of policy forms and rate filings
- Credentialing procedures (other than those affected by specific preemption on provider participation)
- Agent Licensing
- Filing and review of provider contracts
- Enforcement of loss-ratio standards
- Standards and enforcement of commission limitations

Because preemption situations are generally case-specific and often turn on the particular provisions of a State statute, it may be necessary to seek further guidance. For specific guidance on a case-specific question, please contact CMS.