

Your Compliance Program Guide

First Tier, Downstream or Related Entity (FDR) Medicare Advantage (Part C) and Prescription Drug (Part D)



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Introduction

Medical Mutual's Medicare Compliance Program

A trusted insurer for 90 years, Medical Mutual is the oldest and largest health insurance company headquartered in Ohio. We've built our reputation on being trustworthy, honest, caring and ethical. While a lot has changed in providing health benefits over the years, one thing that has not changed is our commitment to these principles.

Our compliance program is designed to meet and build upon the requirements for an effective compliance program found in the United States Sentencing Commission's Guidelines Manual for the sentencing of Organizations¹.

This Compliance Program Guide, which includes specific Compliance Plans, is available to the Board of Directors and all Medical Mutual employees, contractors, subcontractors, vendors, agents, and first tier, downstream, and related entities (FDRs) who provide services for our members.

Serving Our Members Ethically

We're committed to practicing business in an ethical manner. Our Medicare Compliance Program is designed to:

- Reduce or eliminate fraud, waste, and abuse (FWA)
- Ensure we comply with applicable laws, rules and regulations
- Reinforce our commitment to compliance

Using External Entities

As part of the Medicare Advantage (Part C) and Medicare Prescription Drug (Part D) (collectively referred to as "MA/PD") plans that we offer, we contract with several external entities to provide administrative and healthcare services. Some of the services provided by these entities are services that we are required to perform under our contracts with the Centers for Medicare and Medicaid Services (CMS). These external entities that we contract with are referred to as first tier, downstream, and related entities (FDRs).

CMS Requirements Found in this Document

CMS requires that FDRs fulfill specific Medicare Compliance Program requirements, which are described in this document. The Code of Federal Regulations (CFR) outlines these Medicare Compliance Program requirements, which are defined by CMS in their Compliance Program Guidelines².

As an identified FDR of Medical Mutual, you must comply with the requirements established in this Compliance Program Guide.

¹ Chapter 8 of the Guidelines Manual, available at USSC.gov/GuideLines-Manual/2014/2014-Individual-Chapters-and-Guidelines.html.

² Ch. 21, Medicare Managed Care Manual & Ch. 9, Prescription Drug Benefit Manual.

What is an FDR?

We use current CMS definitions to define first tier, downstream and related entities.

First Tier Entity

A first tier entity is any party that enters into a written arrangement, acceptable to CMS, with a Medicare Advantage Organization or Part D plan sponsor or applicant to provide administrative services or healthcare services to a Medicare eligible individual under the Medicare Advantage program or Part D program. (See 42 C.F.R. §§ 422.500 & 423.501).

Downstream Entity

A downstream entity is any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the Medicare Advantage benefit or Part D benefit, below the level of the arrangement between a Medicare Advantage Organization or applicant or a Part D plan sponsor or applicant and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services. (See 42 C.F.R. §§ 422.500 & 423.501).

Related Entity

A related entity is any entity that is related to a Medicare Advantage Organization or Part D sponsor by common ownership or control and:

1. Performs some of the Medicare Advantage Organization's or Part D plan sponsor's management functions under contract or delegation; or
2. Furnishes services to Medicare enrollees under an oral or written agreement; or
3. Leases real property or sells materials to the Medicare Advantage Organization or Part D plan sponsor at a cost of more than \$2,500 during a contract period. (See 42 C.F.R. §§ 422.500 & 423.501).

FDR Examples

The Medicare Compliance Program requirements apply to entities that Medical Mutual contracts with to perform administrative and healthcare services relating to MA/PD contracts with CMS. Some examples of administrative service functions include:

- Sales and marketing
- Utilization management
- Quality improvement
- Applications processing
- Enrollment, disenrollment and membership functions
- Health care services

Examples of healthcare providers contracted with Medical Mutual who participate in our MA/PD networks include physicians, hospitals and other provider types.

Other examples of FDRs include delegates, agents, broker organizations, pharmacies and other individuals, entities, vendors or suppliers contracted with Medical Mutual to provide administrative or healthcare services for our MA/PD Plans. You can find more information in the Medicare Managed Care Manual, Chapter 9, § 40, including the Stakeholder Relationship Flow Charts.

FDR Medicare Compliance Program & Attestation Requirements

It is important that our FDRs are in compliance with applicable laws, rules and regulations. Although we contract with FDRs to provide administrative or healthcare services for our MA/PD Plans, it is ultimately our responsibility to fulfill the terms and conditions of our contract with CMS and meet applicable Medicare program requirements.

Medicare Compliance Program Requirements

As a first tier entity, your organization and all of your downstream entities (if applicable) must comply with the Medicare Compliance Program requirements found in this guide. This guide summarizes your Medicare Compliance Program responsibilities, so it is important to review it each year to ensure you have internal processes to support your compliance with these requirements. The Medicare Compliance Program requirements include, but are not limited to:

1. Fraud, Waste and Abuse (FWA) training, general compliance training
2. Code of Conduct distribution
3. Exclusion list screenings
4. Reporting FWA and compliance concerns to Medical Mutual
5. Offshore operations and CMS reporting
6. Specific federal and state compliance obligations
7. Monitoring and auditing of FDRs.

See the "Toolbox of Resources for FDRs" at the end of this guide. It may help you with meeting these requirements.

Program Non-compliance

If an FDR fails to meet these Medicare Compliance Program requirements, it may lead to

- Development of a corrective action plan
- Retraining
- Termination of your contract and relationship with Medical Mutual

Our actions in response to an FDR's non-compliance will depend on the severity of the compliance issue. If an FDR identifies areas of non-compliance (e.g., refusal of an employee to complete the required FWA training), the FDR must take prompt action to fix the issue and prevent it from happening again.

Attestation Requirements

Each year, an authorized representative from your organization must attest to your compliance with the Medicare Compliance Program requirements described in this guide. You must maintain evidence of your compliance with these Medicare Compliance Program requirements (e.g., employee training records, CMS certificate of FWA training completion, etc.) for no less than 10 years. Medical Mutual and CMS may request that you provide evidence of your compliance with these requirements up to ten years after the event in question. This is for monitoring/auditing purposes.

We take these responsibilities very seriously. If you have questions or concerns about these requirements, please contact one of our business area representatives who will provide guidance or escalate the matter to our Medicare Compliance Officer.

Medicare Compliance Program Requirements

Below you will find more detailed information for each of the Medicare Compliance Program Requirements mentioned in the previous section.

1. Fraud, Waste and Abuse (FWA) Training and General Compliance Training

As a first tier entity, your organization must provide FWA and general compliance training to all of your employees and downstream entities assigned to provide administrative and/or healthcare services for our Medicare plans. To comply with this requirement, you must use the CMS Medicare Parts C & D Fraud, Waste, and Abuse Training and General Compliance Training, or provide equivalent organizational developed training.

Compliance Training Requirements

Regardless of the method used, the training must be completed:

- Within 90 days of initial hire or the effective date of contracting
- At least annually thereafter

Also, you must maintain evidence of training completion for 10 years after conducting the training. Evidence of completion may be in the form of attestations, training logs or other means determined by you to best represent fulfillment of your obligations. For convenience, there are certificates of completion included on the last slides of the CMS Medicare Parts C & D Fraud, Waste, and Abuse Training and General Compliance Training.

The only exception to this training requirement is if your organization is “deemed” to have met the FWA certification requirements through enrollment in Medicare Parts A or B of the Medicare program or though accreditation as a supplier of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). Those parties deemed to have met the FWA training through enrollment in the CMS Medicare Program do not need to complete Part 1: Medicare Parts C and D Fraud, Waste, and Abuse Training. But, they are still obligated to complete Part 2: Medicare Parts C & D Compliance Training.

You can find the training requirements and information regarding deemed status at:

- 42 C.F.R. § 422.503(b)(4)(vi)(C) for Part C
- 42 C.F.R. § 423.504(b)(4)(vi)(C) for Part D
- Medicare Managed Care Manual, Chapter 9 § 50.3

2. Code of Conduct Distribution

Your organization must provide either Medical Mutual's Code of Conduct (COC) and Medicare Advantage Program and Part D Compliance Program Guide or your own comparable COC and Compliance Policies (collectively, "Standards of Conduct") to all employees and Downstream Entities who provide administrative or healthcare services for our Medicare Plans. You must distribute Standards of Conduct:

- Within 90 days of hire or the effective date of contracting
- When there are updates to such Standards of Conduct
- Annually thereafter

Also, you must retain evidence of your distribution of the Standards of Conduct for 10 years after distribution. You can find these Standards of Conduct requirements at:

- 42 C.F.R. § 422.503(b)(4)(vi)(A) for Part C
- 42 C.F.R. § 423.504(b)(4)(vi)(A) for Part D
- Medicare Managed Care Manual, Chapter 9 § 50.1.1

3. Exclusion List Screenings

Federal law prohibits Medicare, Medicaid and other federal healthcare programs from paying for items or services provided by a person or entity excluded from participation in these federal programs. Prior to contracting with Medical Mutual, and monthly thereafter, each first tier entity must check the Office of Inspector General (OIG) and General Services Administration (GSA) "exclusion lists" to confirm that all employees (temporary, permanent, and volunteer) and downstream entities performing administrative or healthcare services for our MA/PD Plans are not excluded from participating in federally-funded healthcare programs. You can use these websites to perform the required exclusion list screening:

- Office of Inspector General (OIG) List of Excluded Individuals and Entities
- General Services Administration (GSA) System for Award Management (SAM)

FDRs must maintain for 10 years evidence that they checked these exclusion lists. You can use logs or other records to document that you've screened each employee and downstream entity in accordance with current laws, regulations and CMS requirements.

If an Employee or Downstream Entity is on the Exclusion List

If any of your employees or downstream entities are on one of these exclusion lists, you must immediately remove them from work directly or indirectly related to our MA/PD Plans and notify us right away.

These exclusion list requirements are noted in § 1862(e)(1)(B) of the Social Security Act, 42 C.F.R. §§ 422.503(b)(4)(vi)(F), 422.752(a)(8), 423.504(b)(4)(vi)(F), 423.752(a)(6), 1001.1901, and further described in the Medicare Managed Care Manual, Chapter 9, § 50.6.8.

4. Reporting FWA and Compliance Concerns to Medical Mutual

The Company is committed to the policy that all employees and FDRs have an obligation to report problems or concerns involving actual or suspected compliance violations.

Reporting Violations

- COMPLIANCE HOTLINE: 1-800-762-8130
- COMPLIANCE CONNECTION: MMO.Ethix360.com/#landing

The Compliance Hotline and Compliance Connection are available to all FDRs, vendors, contractors, agents, providers and business partners as a means to gain additional information or to report violations, or suspected violations, with respect to the relationship between Medical Mutual and the vendor. The Compliance Hotline is a 24-hour hotline. All reports received are kept confidential to the extent practicable. The hotline permits anonymous reporting, and an individual with a question or concern is not required to identify him or herself. It is necessary to provide enough information to enable our Medicare Compliance Officer to initiate an investigation. All reports can be made without fear of retaliation.

5. Offshore Operations and CMS Reporting

To help make sure we comply with applicable federal and state laws, rules and regulations, you're prohibited from using any individual or entity to perform services for our MA/PD Plans if the individual or entity is physically located outside of one of the fifty United States or one of the United States Territories (e.g., American Samoa, Guam, Northern Marianas, Puerto Rico and Virgin Islands). The only exception to this is if an authorized Medical Mutual representative agrees in advance and in writing to the use of an offshore entity.

Notify Medical Mutual Immediately if you Plan to Use an Offshore Entity

Your organization must immediately notify your Medical Mutual business area representative if you plan to use an offshore entity. If your organization performs services offshore or uses an offshore entity to perform services involving the receipt, processing, transferring, handling, storing or accessing of Medicare member protected health information (PHI), and we approve the arrangement, we must submit an attestation to CMS. One example provided by CMS of offshore services that trigger this attestation requirement is "offshore subcontractors that receive radiological images for reading because beneficiary PHI is included with the radiological image and the diagnosis is transmitted back to the U.S."

6. Specific Federal and State Compliance Obligations

Based upon the services that your organization performs for our MA/PD Plans, you may be subject to other federal and state laws, rules and regulations that we didn't describe in this guide. If you have questions about the Medicare compliance requirements for the services that your organization performs, consult your Medical Mutual business area representative.

7. Monitoring and Auditing of FDRs

CMS requires that we develop a strategy to monitor and audit our FDRs. This helps ensure compliance with all applicable laws and regulations and that our first tier entities monitor the compliance of their downstream entities.

Therefore, if you choose to subcontract with other parties to provide administrative or healthcare services for our MA/PD Plans, you must make sure that your downstream entities abide by all laws and regulations that apply to you as a first tier entity. This includes the Medicare Compliance Program requirements described in this guide.

Also, your organization must conduct sufficient oversight to test and ensure that your employees and downstream entities are compliant with applicable laws, retain evidence of completion, conduct root cause analysis and implement corrective action plans or take disciplinary actions, as necessary, to prevent reoccurrence of non-compliance with applicable laws.

Routine Monitoring and Audits

Medical Mutual will monitor its FDRs' activities and performance to ensure that they fulfill their contractual requirements for Medicare Parts C and D, and that they meet established performance standards. We will use multiple methods to monitor and audit FDRs, including risk assessments, on-site audits, desk reviews and monitoring of self-audit reports. We conduct risk assessments to identify the highest risk FDRs and to choose which FDRs to audit. We may conduct these audits using our employees, or we may contract with independent third parties to conduct these audits. Our staff dedicated to FDR monitoring and auditing will employ audits to validate compliance, develop corrective action plans in response to detected offenses and report oversight activities to our Compliance Committee.

If we determine that an FDR does not comply with any of the requirements in this guide, we may require the FDR to develop and submit a Corrective Action Plan (CAP). We can help the FDR address the identified compliance issues, if necessary.

These Monitoring and Auditing requirements are noted in 42 C.F.R. § 422.503(b)(4)(vi)(F) for Medicare Advantage (Part C) and 42 C.F.R. § 423.504(b)(4)(vi)(F) for Part D, and further described in the Medicare Managed Care Manual, Chapter 9 § 50.6.6.

Questions and Concerns

For compliance questions or concerns, please contact your Medical Mutual business area representative. You may also use the Compliance Connection helpline, the online reporting tool found on MedMutual.com, or email us at MACompliance@MedMutual.com.

Resources for FDRs

The grid below provides links to helpful tools and resources.

Monitoring and Oversight	
Downstream Oversight	You must conduct oversight of your downstream entities. You can do this by requesting attestations from your downstream entities to monitor their compliance. Use the criteria listed in the Medical Mutual FDR Annual Attestation.
Check Yourself	You can use the Medical Mutual FDR Attestation to assess your compliance with the Medicare Compliance Program Requirements.
Additional Resources	You can find other resources online. If you have questions about resources that can assist you in meeting the Medicare Compliance Program Requirements, send an inquiry to MACompliance@MedMutual.com .
General Compliance and FWA Training	
Need Compliance Training?	You can take the training located on the Medicare Learning Network (MLN) and download a certificate of completion.
Have Your Own Training?	Verify all required content is contained within your training.
Proof of Training Completion	Document your employee's completion of training from the MLN by using a sign in sheet for attendance of live training; source system screenshots; or a certificate of completion from the training module.
Code of Conduct (CoC) and Policies and Procedures	
Need a Code of Conduct?	You can distribute Medical Mutual's CoC to your employees.
Medicare Compliance Department Policies	Our CoC explains our compliance program, but compliance policies provide more detail about our Medicare Compliance Program.
Exclusion List Screenings	
Where is the OIG list?	Complete OIG exclusion list screenings prior to hire/contracting and monthly thereafter for your employees and downstream entities.
Where is GSA/SAM?	Complete GSA exclusion screenings prior to hire/contracting and monthly thereafter for your employees and downstream entities.
Reporting Resources	
Reporting Non- compliance or Potential FWA to Medical Mutual	Hotline (anonymous): 1-800-762-8130 Medical Mutual FDR Webpage: MedMutual.com/FDR Compliance Connection: MMO.Ethix360.com/#landing



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