

MEDICAL MUTUAL OF OHIO

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

I. Introduction – Medical Mutual’s Medicare Compliance Program

A trusted insurer for more than 80 years, Medical Mutual of Ohio (MMO) is the oldest and largest health insurance company headquartered in the state of Ohio. We’ve built our reputation on trust, honesty, and caring. And while a lot has changed in providing health benefits over the years, one thing that hasn’t changed is our commitment to be trustworthy, honest, and ethical.

Medical Mutual of Ohio’s compliance program is designed to meet and build upon the requirements for an effective compliance program as set forth in the United States Sentencing Commission’s Guidelines Manual for the sentencing of Organizations.¹

MMO makes this Compliance Program Guide, which includes the specific Compliance Plans, 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 its members.

Our Medicare Compliance Program helps us serve 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; and
- Reinforce our commitment to compliance.

We use external entities to bring our members cost-effective healthcare solutions

Medical Mutual of Ohio offers Medicare Advantage (Part C) and Medicare prescription drug (Part D) (collectively referred to as “MA/PD”) plans. We contract with several external entities as a cost effective and efficient means of providing administrative and healthcare services. Some of the services provided by external 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).

You will find specific requirements in this document

CMS requires that MMO’s 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, and they are specifically

¹ See Chapter 8 of the Guidelines Manual, available at <<http://www.uscc.gov/guidelines-manual/2014/2014-individual-chapters-and-guidelines.html>>.

defined by CMS in their January 11, 2013 release of the Compliance Program Guidelines.²

It is important for you to follow these requirements

You received this Compliance Program Guide because we've identified you as an FDR. This means that you must comply with the requirements established in this Guide.

II. What is an FDR?

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

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 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 means 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).

FDRs providing administrative or healthcare services

The Medicare Compliance Program requirements apply to entities with which MMO contracts to perform administrative and health care services relating to MA/PD contracts with CMS. Some examples of administrative service functions include:

- Sales and marketing;

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

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

Examples of health care providers contracted with MMO to participate in our MA/PD network 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 MMO to provide administrative or health care 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.

III. 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 health care services for our MA/PD Plans, MMO is ultimately responsible for fulfilling the terms and conditions of our contract with CMS and meeting applicable Medicare program requirements.

Compliance program requirements

First tier entities are responsible for making sure that their downstream entities comply with applicable laws and regulations, including the requirements in this Compliance Program Guide. As a first tier entity, your organization and all of your downstream entities (if applicable) must comply with these Medicare Compliance Program requirements. This Guide summarizes your Medicare Compliance Program responsibilities. Please review this Guide each year to make sure that you have internal processes to support your compliance with these requirements. These Medicare Compliance Program requirements include, but are not limited to:

- A. Fraud, Waste and Abuse (FWA) training, general compliance training and Code of Conduct distribution;
- B. Exclusion list screenings;
- C. Reporting FWA and compliance concerns to MMO;
- D. Offshore operations and CMS reporting;
- E. Specific federal and state compliance obligations; and
- F. Monitoring and auditing of FDRs.

Also, see the “Toolbox of Resources for FDRs” at the end of this Guide. It may help you with meeting these requirements.

What may happen if you do not comply?

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

- Development of a corrective action plan;
- Retraining; and/or
- Termination of your contract and relationship with MMO.

Our actions in response to an FDR's non-compliance will depend on the severity of the compliance issue. If a 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. MMO 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, contact the appropriate MMO business area representative who will provide guidance or escalate the matter to the MMO Medicare Compliance Officer. What follows is a description of each Medicare Compliance Program requirement.

A. Fraud, Waste and Abuse (FWA) training, general compliance training and Code of Conduct distribution

FWA 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 health care services for MMO's 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; and
- At least annually thereafter.

Also, you must maintain evidence of training completion for ten 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 into Medicare Parts A or B of the Medicare program or through accreditation as a supplier of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). Those parties deemed to have met the FWA training through enrollment into 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; and
- Medicare Managed Care Manual, Chapter 9 § 50.3.

You must give your employees Standards of Conduct

Your organization must also provide either MMO’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 health care services for MMO’s 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; and
- 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; and
- Medicare Managed Care Manual, Chapter 9 § 50.1.1.

B. Exclusion list screenings

Federal law prohibits Medicare, Medicaid and other federal health care programs from paying for items or services provided by a person or entity excluded from participation in these federal

programs. Therefore, prior to contracting with MMO 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 health care services for MMO’s MA/PD Plans are not excluded from participating in federally-funded health care programs. You can use these websites to perform the required exclusion list screening:

- [Office of Inspector General \(OIG\) List of Excluded Individuals and Entities; and](#)
- [General Services Administration \(GSA\) System for Award Management \(SAM\).](#)

Also, 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.

You must take action if an employee or downstream entity is on the 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 MMO’s 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.

C. 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: <https://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 vendor relationship between MMO 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, however, that enough information be provided to enable

MMO's Medicare Compliance Officer to initiate an investigation. All reports can be made without fear of retaliation.

D. Offshore operations & 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 MMO's 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 MMO representative agrees in advance and in writing to the use of such offshore entity.

Notify MMO immediately if you plan to use an Offshore Entity

Your organization must immediately notify your MMO 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 MMO approves the arrangement, MMO 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 personal health information (PHI) is included with the radiological image and the diagnosis is transmitted back to the U.S."

E. Specific federal and state compliance obligations

Based upon the services that your organization performs for MMO's 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 MMO business area representative.

F. 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 health care services for MMO's 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.

Expect routine monitoring and audits

Medical Mutual of Ohio will monitor its FDRs' activities and performance to ensure that they fulfill their contractual requirements for Medicare Parts C and Part D and that they meet established performance standards. MMO will use multiple methods to monitor and audit FDRs, including risk assessments, on-site audits, desk reviews and monitoring of self-audit reports. MMO conducts risk assessments to identify the highest risk FDRs in order to choose which FDRs to audit. MMO may conduct these audits using its employees, or it may contract with independent third parties to conduct these audits. MMO 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 MMO's Compliance Committee.

If MMO determines that an FDR does not comply with any of the requirements in this Guide, we will 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/Concerns

For compliance questions or concerns, please contact your MMO business area representative. You may also use the Compliance Connection helpline, the on-line reporting tool found on Medmutual.com, or via email to MACompliance@medmutual.com.

Toolbox of 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 MMO FDR Annual Attestation to ensure those with whom you contract (and touch MMO's Medicare business)
Check yourself	You can use the MMO FDR Annual Attestation to assess your compliance with the Medicare Compliance Program Requirements.
Other tools	
More tools	You can find other resources online. If you have ideas for tools that would assist you in meeting the Medicare Compliance Program Requirements, send an email to MACompliance@medmutual.com .
General compliance and FWA training	
Don't have training in place?	No need to develop your own. You can download the CMS General Compliance and FWA training . Also, you can take the training online (after registration) on the Medicare Learning Network .
Already have your own training in place?	Verify all content contained in the CMS published training is included.
Proof of training completion	Document your employee's completion of CMS's General Compliance and Fraud Waste and Abuse Training. Use sign in sheet to verify attendance, attach materials used during training, and document effectiveness of training via testing or
Code of Conduct and compliance policies	
Don't have your own code?	If not, feel free to distribute MMO's Code of Conduct to your employees.
Medicare compliance department policies	Our Code of Conduct explains our compliance program, but these policies provide more detail about our Medicare Compliance Program.
Share our Code and policies	Use this announcement template to share MMO's Code of Conduct and compliance policies.
Exclusion list screenings	
Where is the OIG?	Complete OIG exclusion list screenings prior to hire/contracting and monthly thereafter for your employees and downstream entities.
Where is the GSA/SAM?	Complete GSA exclusion list screenings prior to hire/contracting and monthly for your employees and
Reporting mechanisms	
How do I report non-compliance or potential fraud, waste, and abuse (FWA) to MMO?	This chart provides ways for reporting issues that impact MMO directly to MMO. Feel free to share this throughout your organization so that your employees know how to report concerns. Remember, you must report suspected or detected