

Frequently Asked Questions

First Tier, Downstream or Related Entity (FDR)



Contents

FDR General Compliance; Fraud, Waste, and Abuse (FWA) Training; Code of Conduct

1. Why am I receiving notice to complete training for Medical Mutual?	3
2. Why is this training necessary?	3
3. What does CMS mean by an FDR?	3
4. What Medical Mutual products/plans does this training apply to?	3
5. What if I do not contract with Medical Mutual for its Medicare products?	3
6. Who must take this training?	4
7. Do all employees of every FDR have to satisfy FWA training requirements?	4
8. How do I know if I am deemed to have met the FWA training requirements already?	4
9. If I am deemed, am I exempt from these requirements completely?	4
10. What are the Medicare Compliance training requirements?	4
11. What is a Code of Conduct?	4
12. How does Medical Mutual’s Code of Conduct relate to this training?	4
13. Can an FDR use its own Code of Conduct?	4
14. Where can the Medical Mutual Code of Conduct be found?	4
15. Do we have to use Medical Mutual’s training, or can we use a different version of training?	5
16. How often does this training have to be taken?	5
17. When does the training have to be completed?	5
18. What kind of documentation is needed to show training was completed?	5
19. What documentation does Medical Mutual need after completion of this training?	5
20. What happens if I don’t complete the required training?	5
21. What is the source of these requirements?	5
22. Are these requirements new?	6
23. Who should I contact if I have more questions about this training?	6

Reporting Potential or Actual Non-Compliance or FWA

24. Do we have to report non-compliance and FWA to Medical Mutual or does Medical Mutual consider reporting within our organization to be sufficient?	6
25. What should I do if I suspect fraud, waste, or abuse or other compliance issues?	6

Sanction, Debarment, Exclusion Lists

<u>26. What is the OIG exclusion list?</u>	6
<u>27. What is the difference between the OIG LEIE, General Services Administration (GSA) Excluded Parties List System (EPLS), and the System for Award Management (SAM) Websites?</u>	7
<u>28. What are my requirements related to Federal health care program exclusion and debarment checks?</u>	7
<u>29. How often do the exclusion/debarment checks have to be completed?</u>	7
<u>30. What evidence should I submit to show that these checks are completed?</u>	7
<u>31. What if an individual or entity is identified on one of the exclusion/debarment lists?</u>	7

Validation/Audit of Effective Compliance Program Requirements

<u>32. What documentation/evidence will CMS and/or Medical Mutual ask FDRs for to support their compliance with Medical Mutual’s Compliance Program?</u>	7
<u>33. Why is Medical Mutual asking for all this information?</u>	8
<u>34. Why are you asking about how long I retain my employee training and disciplinary records?</u>	8
<u>35. Why are you asking about my subcontractors (i.e., downstream contractual arrangements)?</u>	8
<u>36. What oversight is expected for my subcontractors?</u>	8

Offshoring

<u>37. Why is Medical Mutual asking about offshore entities?</u>	8
<u>38. What areas are considered offshore?</u>	8
<u>39. What does offshore subcontractors mean?</u>	8
<u>40. How do Providers notify Medical Mutual that they utilize an offshore entity?</u>	9

FDR General Compliance; Fraud, Waste, and Abuse (FWA) Training; Code of Conduct

1. Why am I receiving notice to complete training for Medical Mutual?

Because of your contractual relationship with Medical Mutual, you are considered an FDR and are required to ensure that you, your employees, and any Downstream and Related Entity employees complete this training.

2. Why is this training necessary?

The Centers for Medicare and Medicaid Services (CMS) require Medicare Advantage Organizations and Part D sponsors to ensure that general compliance and fraud, waste, and abuse training and education is communicated to their First Tier, Downstream, and Related Entities (FDRs) who are involved in the administration or delivery of Parts C and D benefits. Because of your contractual relationship with Medical Mutual, you are considered an FDR. Therefore, CMS requires that you, your employees, and any Downstream and Related Entity employees complete this training.

3. What does CMS mean by an FDR?

CMS defines First Tier, Downstream and Related entities (FDR) as:

First Tier Entity

Any party that enters into a written arrangement, acceptable to CMS, with a Medicare Advantage Organization (MAO) 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.

Downstream Entity

Any party that enters into a written agreement, acceptable to CMS, with persons or entities involved with the Medicare Advantage or Part D benefit, below the level of first tier entity. These arrangements continue down to the level of the ultimate provider of both health and administrative services.

Related Entity

Any entity that is related to an MAO or Part D Sponsor by common ownership or control and (1) performs some of the sponsor's management functions under contract or delegation; (2) furnishes services to Medicare enrollees under an oral or written agreement; or (3) leases real property or sells materials to the MAO or Part D plan sponsor at a cost of more than \$2500 during a contract period.

4. What Medical Mutual products/plans does this training apply to?

These requirements apply to all Medical Mutual Part C and Part D Medicare products.

5. What if I do not contract with Medical Mutual for its Medicare products?

This training does not apply to you unless you are contracted with another entity that is contracted with Medical Mutual to service our Medicare products.

6. Who must take this training?

You, your employees, and any of your Downstream and/or Related Entity employees that are involved in the delivery of our Medicare product administration or services must take this training. It is your responsibility to identify those parties that serve in this capacity and ensure they complete the training. The only exception is if they are deemed exempt by CMS from the Fraud, Waste, and Abuse (FWA) training.

7. Do all employees of every FDR have to satisfy FWA training requirements?

FDR employees who perform work on behalf of our Medicare products must satisfy CMS FWA Training requirements unless the employees are deemed to have met the FWA training requirements.

8. How do I know if I am deemed to have met the FWA training requirements?

FDRs who have met the FWA certification requirements through enrollment into Parts A or B of the Medicare program or through accreditation as a supplier of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) are deemed to have met the CMS FWA training requirements. Deeming is at the level of the entity's participation/accreditation (whether for the individual or entire organization).

9. If I am deemed, am I exempt from these requirements completely?

No. This deeming status is applicable only to the FWA training, so all other requirements still apply (e.g., Code of Conduct distribution to your employees and Downstream and/or Related Entities).

10. What are the Medicare Compliance training requirements?

The Medicare Managed Care Manual Chapter 21 states that Plan Sponsors, and their FDRs, are required to have General Program and Fraud, Waste and Abuse training within 90 days of hire/contract and annually thereafter.

11. What is a Code of Conduct?

A "Code of Conduct," also known by other similar names, states the overarching principles and values by which the company operates, and defines the underlying framework for the compliance policies and procedures. It communicates the expectations that all employees must conduct themselves in an ethical manner with issues of noncompliance and potential FWA required to be reported through appropriate mechanisms. CMS requires the communication of this document to employees and FDR employees that service our Medicare products. We have developed and maintain the Medical Mutual Code of Conduct.

12. How does Medical Mutual's Code of Conduct relate to this training?

CMS requires that FDRs and their employees receive a Code of Conduct (either Medical Mutual's or the FDR's equivalent code).

13. Can an FDR use its own Code of Conduct?

Yes, if it is equivalent to the Medical Mutual Code of Conduct.

14. Where can the Medical Mutual Code of Conduct be found?

You can access our Code of Conduct at MedMutual.com > About Us > Compliance Information.

15. Do we have to use Medical Mutual's training, or can we use a different version of training?

Medical Mutual's FWA training and Code of Conduct, or an equivalent version, may be used to satisfy the training requirements.

16. How often does this training have to be taken?

Initial training must be completed, and then annually thereafter.

17. When does the training have to be completed?

Training must be completed within 90 days of an employees' initial hire date, and at least annually thereafter. Your Downstream and/or Related Entities must also be trained within this same timeframe.

18. What kind of documentation is needed to show training was completed?

Evidence may be in the form of employee attestations, employee attendance/training logs, or other means determined by you to best represent fulfillment of your obligations. You should retain evidence of completion for at least ten years. Medical Mutual and/or CMS may request this evidence to ensure completion of these requirements. If you and/or your employees are deemed to have met the FWA training requirements, you should retain proof of the deemed status. Medical Mutual and/or CMS may request this evidence to ensure completion of these requirements.

19. What documentation does Medical Mutual need after completion of this training?

Medical Mutual collects attestations to confirm completion of the training requirements. Depending on the type of First Tier that you are for us, you may receive the request by email or in another manner. You must also maintain evidence to document the completion of this training for all your employees and Downstream and/or Related Entities' employees.

20. What happens if I don't complete the required training?

If an issue of noncompliance is determined, enforcement actions may be taken to fix the issue and prevent future occurrences. Enforcement actions may vary depending upon the severity of the issue but could include corrective action plans and contract termination.

As expressed within our Medicare Advantage and Part D Compliance Program, it is expected that you ensure timely, consistent and effective enforcement through well-publicized disciplinary standards. As a Medical Mutual First Tier Entity, you are expected to enforce completion of these requirements with your Downstream and/or Related Entities.

If you are aware of or suspect noncompliant, unethical or illegal behavior by others, including, but not limited to, failure to complete the required training and education, you are obligated to report it to us immediately so that we can investigate and respond appropriately. (See question #25 for reporting mechanism options.)

21. What is the source of these requirements?

The Code of Federal Regulations (CFR) outlines these regulatory requirements at 42 CFR §§ 422.503 and 423.504. These requirements are further described within the Medicare Managed Care Manual, Chapters 9 and 21.

22. Are these requirements new?

No. These regulatory requirements from CMS are not new requirements. If you have participated in a prior Medicare Advantage Part C or Part D Sponsor plan, you would have previously received similar training notices regarding these requirements.

23. Who should I contact if I have more questions about this training?

If you have any questions related to the notices you've received about training, you should contact your Medical Mutual representative.

Reporting Potential or Actual Non-Compliance or FWA

24. Do we have to report non-compliance and FWA to Medical Mutual or does Medical Mutual consider reporting within our organization to be sufficient?

All concerns that affect our Medicare products must be reported to us but may go through your internal process initially. It is mandatory to report any potential or actual non-compliance and/or FWA to us. There is a zero-tolerance policy for retaliation or retribution against anyone who reports suspected misconduct.

FDRs must utilize a system that promptly responds to compliance and FWA concerns. FDRs must also include thorough investigations, root cause analyses, corrective actions and reporting to authorities, as applicable.

25. What should I do if I suspect fraud, waste, or abuse or other compliance issues?

If you identify compliance issues or potential fraud, waste, or abuse, please report it to us immediately so that we can investigate and respond appropriately. There are mechanisms in place that may be used to report issues such as the Compliance Helpline at 1-800-762-8130 or our Compliance Connection website at MMO.Ethix360.com/#landing. These reporting mechanisms are outlined in our Medicare Advantage and Part D Compliance Plan. We enforce a zero-tolerance policy for retaliation or retribution against anyone who reports suspected misconduct.

Sanction, Debarment, Exclusion Lists

26. What is the OIG exclusion list?

The Office of the Inspector General (OIG) List of Excluded Individuals and Entities (LEIE list) and the General Services Administration (GSA) Excluded Parties List System (EPLS) provide information to the healthcare industry, patients and the public regarding individuals and entities currently excluded from participation in Medicare and other Federal healthcare programs. The effect of an exclusion is that no payment will be made by any Federal healthcare program for any items or services furnished, ordered or prescribed by an excluded individual or entity. No program payment will be made for anything that an excluded person furnishes, orders, or prescribes. CMS prohibits payments by us directly or indirectly to anyone on the LEIE list or the EPLS. For more information on the OIG LEIE, see OIG.HHS.gov/Exclusions/Index.asp.

27. What is the difference between OIG's LEIE and the EPLS?

OIG's LEIE includes all healthcare providers and suppliers that are excluded from participation in federal healthcare programs, including those providers and suppliers that might also be on the EPLS. In addition to healthcare providers (that are also included on the OIG LEIE) the EPLS includes non-healthcare contractors.

28. What are my requirements related to Federal healthcare program exclusion and debarment checks?

First Tier, Downstream, and Related Entities must review the LEIE list and the EPLS prior to the hiring or contracting of any new employee, temporary employee, volunteer, consultant, governing body member, or FDR, and monthly thereafter, to ensure that none are excluded from participating in federal programs. For more information or access to the publicly accessible online databases, please see the following links:

For OIG LEIE

[OIG.HHS.gov/Exclusions/index.asp](https://oig.hhs.gov/Exclusions/index.asp)

For GSA

[SAM.gov](https://sam.gov).

29. How often do the exclusion/debarment checks have to be completed?

The checks must be completed initially before hiring/contracting and then monthly thereafter.

30. What evidence should I submit to show that these checks are completed?

The documentation or evidence may vary depending on the system used to complete the checks. If you perform a manual search of the website lists, you may use a screen print of the results. If you perform the checks using a more automated system or program, your documentation may be based on the information available within that system. Regardless of the process you use to perform the required checks, the documentation to verify compliance with the requirements should clearly identify the name of the entity or individual checked, the date the check was performed, and the results of the check.

31. What if an individual or entity is identified on one of the exclusion/debarment lists?

If you identify an excluded individual or entity employed or contracted by your organization, you must report this to us. This entity must be immediately removed from directly or indirectly servicing our Medicare products.

Validation/Audit of Effective Compliance Program Requirements

32. What documentation/evidence will CMS and/or Medical Mutual ask FDRs for to support their compliance with our Compliance Program?

FDRs must have documentation to show they are compliant with each requirement. Examples include, but are not limited to, policies and procedures, training logs and attestations.

33. Why is Medical Mutual asking for all this information?

CMS requires that we conduct oversight of contracted entities to ensure that they are meeting CMS compliance expectations for all Part C & D related responsibilities. You are required to provide documentation at the request of Medical Mutual or CMS, as depicted within your contractual agreement. Please note that CMS requires your evidence of training completion to be at the level of your employees (i.e., employee training logs, sign-in sheets, employee attestations, etc.).

34. Why are you asking about how long I retain my employee training and disciplinary records?

CMS requires that records are retained for at least ten years and that we validate your compliance.

35. Why are you asking about my subcontractors (i.e., downstream contractual arrangements)?

CMS requires that we assess your oversight of your subcontractors who service our Medicare Advantage and Part D products. These assessments are required to ensure that you have processes to validate their compliance and impose corrective actions when issues are identified.

36. What oversight is expected for my subcontractors?

CMS requires that your organization and any of your Downstream and Related Entities maintain compliance with all CMS requirements, as applicable, while servicing our Medicare Advantage and Part D products. This includes the requirements already mentioned, as well as any others that may apply that are not listed in this FAQ document. For example, CMS requires the reporting and oversight of all entities that manage Protected Health Information (PHI) offshore. Therefore, it is expected that you identify any such services for your organization or any of your Downstream and Related Entities in order to conduct oversight of those processes. If you use Downstream and/or Related Entities, you must ensure that proper oversight is conducted through ongoing monitoring and audits.

Offshoring

37. Why is Medical Mutual asking about offshore entities?

MA organizations such as Medical Mutual are required to provide CMS with information about FDRs who utilize or employ offshore entities that store or access protected health information (PHI).

38. What areas are considered offshore?

For this purpose, the term offshore refers to any country that is not within the United States or one of the United States territories of American Samoa, Guam, Northern Marianas, Puerto Rico and the Virgin Islands.

39. What does offshore subcontractors mean?

Offshore subcontractors provide services that are performed by workers located in offshore countries, regardless of whether the workers are employees of American or foreign companies. Subcontractors that are considered offshore can be either American-owned companies with certain portions of their operations performed outside the United States or foreign-owned companies with their operations performed outside the United States.

40. If I am a provider, how do I notify Medical Mutual if I utilize an offshore entity?

Please complete and sign the Provider FDR Offshore Attestation and return it to us. The Offshore Attestation can be obtained by contacting your Provider Contracting Manager or at [MedMutual.com/For-Providers/First-Tier-Downstream-or-Related-Entities.aspx](https://www.MedMutual.com/For-Providers/First-Tier-Downstream-or-Related-Entities.aspx).



MEDICAL MUTUAL®

100 American Road
Cleveland, OH 44144-2322

MedMutual.com