



## Frequently Asked Questions (FAQs) for First Tier, Downstream and Related Entities (FDRs) Compliance Program Requirements

These FAQs were developed for Quartz's FDRs. They summarize common questions and answers about Medicare compliance program requirements. These requirements are further explained in more detail in the Quartz Medicare Advantage FDR Compliance Program Requirements Guide. FDRs can also access Quartz's FDR webpage [here](#) for more information.

### I. General questions

#### 1. What does FDR mean?

FDR stands for first tier, downstream and related entities. If you perform an administrative or health care service function on behalf of Quartz's Medicare Advantage business, then you are classified as an FDR.

Examples of FDRs include providers contracted to provide services to our Medicare Advantage members, sales agents contracted to market and sell our Medicare Advantage products, vendors providing administrative services for our Medicare Advantage members/products and delegated entities contracted to make decisions on our behalf for our Medicare Advantage members/products.

The Centers for Medicare & Medicaid Services (CMS) defines FDRs as:

- **First Tier Entity** - Any party that enters into a written agreement, acceptable to CMS, with an Medicare Advantage Organization (MAO) or Part D plan sponsor or applicant to provide administrative services or health care services to a Medicare eligible individual under the Medicare Advantage (MA) 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 MA benefit or a Part D benefit, below the level of the arrangement between an MAO 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.
- **Related Entity** – This refers to any entity that is related to an MAO or Part D Sponsor by common ownership or control and:
  1. Performs some of the MAO or Part D plan 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 material to the MAO or Part D plan sponsor at a cost of more than \$2,500 during a contract period.

#### 2. What Quartz products, plans, and providers do these requirements apply to?

We offer Medicare Advantage (MA) and Prescription Drug (Part D) coverage to eligible members. These requirements apply to all entities that participate in any of these plans:

- Medicare Advantage (MA)
- Prescription Drug (MAPD)

- 3. I am a provider for Original Medicare (Parts A or B). Do compliance program requirements apply to me?**  
If you are a provider that accepts Original Medicare (Part A and B) and contracts with Quartz to provide services to our Medicare Advantage members, then these requirements apply to you. This includes, but not limited to: individual providers, ancillary providers, dentists, behavioral health, group practices, facilities, hospitals, delegated entities, etc.

These requirements apply to you if you are contracted to provide an administrative or health care service function to our Medicare Advantage members. If you are unsure of your contracting status with us, please contact us at [QuartzFDR@quartzbenefits.com](mailto:QuartzFDR@quartzbenefits.com).

- 4. What if I do not service or accept Medicare Advantage plan members? Am I still required to complete the Annual FDR Compliance Attestation?**

If you received a notice, you are participating in our Medicare Advantage plans. Whether you see or do not see members in these plans these requirements apply to you or your organization.

The [Medicare Advantage FDR Annual Compliance Attestation](#) is requested from our FDRs to verify that you have received the Medicare Compliance Program requirements and that you are compliant with these requirements. Failure to complete the attestation may result in additional action up to termination of contract.

- 5. What is the source of these requirements?**

These regulatory requirements are from CMS. CMS requires FDRs to satisfy specific Medicare compliance program requirements. They are described within the [Medicare Managed Care, Chapter 21-Compliance Program Guidelines](#) and [Prescription Drug Benefit Manual, Chapter 9-Compliance Program Guidelines](#), updated by CY 2015 Final Rule CMS-4159-F published May 23, 2014.

- 6. Are the requirements new?**

No, these requirements are not new. As an FDR, you and/or your organization and all your downstream entities must comply with Medicare compliance program requirements. There have been changes to these requirements since they were implemented. If you are not familiar with the requirements, please review our Medicare Advantage FDR Compliance Program Requirements Guide found under FDR Resources [here](#).

- 7. What will happen if I don't comply with all the Medicare compliance program requirements? Who do we report this to? Will we be terminated?**

If you or your organization is not meeting the requirements, you should contact your Quartz contract manager or contract coordinator.

If you are willing to comply with the requirements, your contract will not be terminated. Instead, we will work with you to resolve the issue. We will provide training and education on these requirements and we will ensure you implement a corrective action plan (CAP) to ensure you comply. We will ask that you provide a written CAP that addresses the issue and outlines and the actions you will complete to be compliant.

- 8. Why am I receiving a notice to complete an attestation?**

If you are asked to complete a [Medicare Advantage FDR Annual Compliance Attestation](#), then we identified you as a first tier entity because of your contractual relationship with us. CMS requires us to have oversight of our FDRs. Part of this oversight includes collection of an attestation to confirm that you understand and are complying with Medicare compliance program requirements.

- 9. I have no employees. Do I have to complete an attestation?**

Yes, you should submit an attestation even if you have no employees. This includes solo practitioners, agents, sales partners, etc.

**10. Does each staff member have to complete an attestation? Who is required to complete the attestation?**

No. An authorized representative must complete and submit an attestation on behalf of your organization. We describe who might be an authorized representative in Medicare Advantage FDR Compliance Program Requirements Guide found under FDR Resources [here](#).

**11. How often do I have to complete the attestation?**

The [Medicare Advantage FDR Annual Compliance Attestation](#) is due annually each year as part of our oversight of FDRs.

**12. What documentation must I keep showing compliance with these Medicare compliance program requirements.**

You must have documentation to show you are compliant with each requirement. Please reference our [Evidence Examples](#) table that provides examples of the types of evidence that may be requested by us and CMS.

**13. Who do I contact if I have questions?**

If you have questions about the Medicare Compliance Program requirements that are not addressed in our Medicare Advantage FDR Compliance Program Guide you can submit your questions to [QuartzFDR@quartzbenefits.com](mailto:QuartzFDR@quartzbenefits.com)

**II. General compliance and fraud, waste and abuse (FWA) training**

**14. Why is it necessary for you to provide general compliance and FWA training to all applicable employees and downstream entities?**

As a first tier entity, your organization must provide general compliance and FWA training to all applicable employees and downstream entities assigned to provide administrative and/or health care services for Quartz's Medicare Advantage business.

CMS no longer requires FDRs to complete its Medicare Parts C and D General Compliance and Combating Medicare Parts C and D Fraud, Waste, and Abuse Training. Instead, you may complete your own version of general compliance and FWA training specific to your organization's needs.

**15. When must trainings/education be completed?**

Required training/education must be completed:

- Within 90 days of hire or effective date of contracting;
- When material are updated; and
- Annually thereafter.

**16. What kind of documentation is needed to show training/education was completed?**

Documentation must include employee names, dates of completion and scores (if captured). Evidence of completion may be in the form of:

- Attendance sheets
- Training logs
- Certificates
- Attestations
- Electronic acknowledgements

You must keep maintain evidence/records of training completion for a minimum of 10 years. Quartz and may request this evidence to ensure completion of the training. If you are deemed and except from FWA training requirements, you must retain evidence of your deemed status.

**17. Can an FDR be deemed (exempt) from having to provide general compliance and FWA training or its employees and downstream and related entities?**

Only FWA training/education can be deemed for FDRs that meet the FWA certification requirements through enrollment into Parts A or B of the Medicare program or through DMEPOS accreditation. FDRs deemed from providing FWA training must still provide general compliance training and meet other CMS compliance program requirements found in our Medicare Advantage FDR Compliance Program Requirements Guide found under FDR Resources [here](#).

### **III. Code of Conduct and compliance policies**

**18. What is a Code of Conduct?**

Code of Conduct also known in some organizations as the “Standards of Conduct.” It is the all-encompassing principles and values by which the company operates, and defines the structure of the compliance program.

**19. How often must the Code of Conduct be distributed?**

Your Code of Conduct and/or compliance policies must be distributed to employees:

- Within 90 days of hire
- Annually
- When changes are made

**20. Can I use my own Code of Conduct?**

Yes, you can use your own Code of Conduct and compliance policies. They must contain elements set forth in Section 50.1 and its subsection of Chapters 9 of the Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual. It must also express the entity’s commitment to comply with federal and state laws, ethical behavior and compliance program operations.

If you don’t have your own Code of Conduct and compliance policies, you can disseminate Quartz’s [Code of Conduct](#) and [applicable compliance program policies](#).

### **IV. Exclusion lists screenings**

**21. What are the exclusion lists FDRs must verify and where do I find them?**

There are two exclusion lists you must check:

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

**22. What is the difference between the OIG LEIE and GSA SAM?**

GSA SAM includes exclusion and debarment actions taken by various federal agencies. The OIG only contains the exclusion actions taken by the OIG. You must screen both.

**23. What are the requirements related to exclusion list screenings?**

FDRs must review both the [OIG](#) and [GSA SAM](#) exclusion lists. Review of both these lists are required prior to hire or contracting and monthly thereafter. Screening “upon hire” does not meet the requirement. We explain this requirement in more detail within the Medicare Advantage FDR Compliance Program Requirements Guide.

Monthly screenings are essential to ensure your employees and downstream entities are not excluded from participating in federal health care programs, and to prevent inappropriate payment to providers, pharmacies, and other entities that have been added to exclusion lists since the last time the list was checked. Federal money cannot be used to pay for services provided or prescribed by an excluded person or entity.

**24. How often do the exclusion lists screenings have to be completed?**

Both the [OIG](#) and [GSA SAM](#) exclusion lists must be checked before hiring/contracting and monthly thereafter.

**25. What evidence must I keep to show that these checks were completed?**

The documentation may vary depending on how you complete the screenings. If you perform these checks using an automated system or program, your documentation may be based on the information available within that system.

Regardless of the system or process you use to do these checks; your documentation must demonstrate:

- Which exclusion list(s) were checked
- Date the check was completed
- Names of the individuals and entities that were checked
- Results of the check, and

**26. What should I do if an individual or entity is identified as excluded?**

You should immediately stop them from doing any work on Quartz's Medicare Advantage business. You should also report this to Quartz.

## V. Record Retention

**27. How long do I need to maintain records?**

FDRs must maintain records of Medicare compliance program requirements for a minimum of 10 years.

Examples include:

- Employee training records
- Distribution of the Code of Conduct or compliance policies
- OIG/GSA SAM exclusion list screenings
- Reports of and responses to suspected noncompliance and/or FWA
- Auditing and monitoring activities and any corrective actions taken

An FDRs inability to produce documentation may result in a request for corrective action or other contractual remedies. Be sure that your organization has a policy in place that outlines your organization's documentation policy and process. Also ensure your policy is shared and understood by employees, and that all Medicare compliance program documentation is retained for at least 10 years.

## VI. Reporting Mechanisms

**28. What is Fraud, Waste & Abuse (FWA)?**

**Fraud:** Is the intentional deception or misrepresentation made by an individual, knowing that the misrepresentation could result in some unauthorized benefit to them or to others. The most common kind of fraud involves false statements or deliberate omission of information that is critical in the determination of authorization and payment for services.

**Waste:** Overutilization of services or other practices that, directly or indirectly, result in unnecessary cost to the healthcare system, including Medicare and Medicaid programs. It is not considered to be caused by criminally negligent actions, but by misuse of resources.

**Abuse:** Payment for items or services when there is not legal entitlement to that payment and the individual or entity has not knowingly and/or intentionally misrepresented facts to obtain payment.

**Medicare Fraud and Abuse Laws:** Federal laws governing Medicare fraud and abuse include all of the following:

- Federal False Claims Act (FCA)
- Anti-Kickback Statute (AKS)
- Physician Self-Referral Law (Stark Law)
- Social Security Act

**29. Do we have to report noncompliance and FWA to Quartz?**

Yes. Your internal processes must include a process to report concerns to Quartz. You must notify Quartz about any actual or potential noncompliance and FWA if it impacts our Medicare Advantage business.

Quartz’s FDRs can make reports using the mechanisms found the Quartz [Code of Conduct](#). We have a zero-tolerance policy for retaliation or intimidation against anyone who reports a concern in good faith.

If you don’t have internal reporting mechanisms, you can share our [Compliance and FWA Reporting Poster](#) with your employees and downstream entities so they can report concerns directly.

**30. What can I do if I suspect FWA or noncompliance?**

You must report the issue to us so we can investigate and respond to it immediately. Our [Compliance and FWA Reporting Poster](#) describes a ways you can make a report.

As a Quartz Medicare Advantage FDR, you can make reports using any of the mechanisms listed in the Quartz [Code of Conduct](#). Don’t worry about retaliation. We enforce a zero-tolerance policy for retaliation against anyone who reports suspected misconduct.

## **VII. Downstream entity oversight**

**31. Which of my subcontractors should be considered downstream entities?**

Not every subcontractor is considered a Downstream Entity. Only those entities who provide administrative or health care services for Quartz Medicare Advantage business are Downstream Entities. FDRs should have processes in place to identify and classify subcontractors as Downstream Entities.

**32. Why are we asking about my downstream entities (i.e. subcontractors)?**

We are accountable to CMS for all our FDRs. If you are subcontracting, then we need to ensure you are doing appropriate oversight of your downstream entities.

**33. What requirements apply to downstream entities?**

Downstream entities must comply with applicable regulatory requirements that apply to the Medicare Part C and D program. This includes the compliance program requirements further explained in our Medicare Advantage FDR Compliance Program Guide found under FDR Resources [here](#).

### **34. What oversight is expected for my downstream entities?**

If you utilize downstream entities, you must oversight of their compliance and performance. This includes testing compliance program requirements and performance of your downstream entities through auditing and monitoring and requesting corrective actions when deficiencies are identified.

## **IX. Offshore Subcontractors**

### **35. What is an offshore subcontractor?**

CMS considers MA organizations and PDP sponsors to be “contractors” with respect to CMS for the purposes of delivering Medicare Part C and Part D benefits. The term “subcontractor” refers to any organization that a sponsor contracts with to fulfill or help fulfill requirements in their Parts C and/or Part D contracts. Subcontractors include all first tier, downstream, and/or related entities.

The term “offshore” refers to any country that is not on the fifty United States or one of the United States Territories (American Samos, Guam, Northern Marianas, Puerto Rico, and Virgin Islands). Examples of countries that meet the definition of “offshore” include: Mexico, Canada, India, Germany, and Japan. Subcontractors that are considered offshore can be either American-owned companies with certain portions of their operations performed outside of the United States or foreign-owned companies with their operations performed outside of the United States. Offshore subcontractors provide services performed by workers located in offshore countries, regardless of whether the workers are employees of American or foreign companies.

### **36. Does your organization have to disclose offshore subcontractor information or offshore staff if the subcontractor or staff will be performing a function that supports our contract with Quartz?**

Yes. If FDRs perform services offshore or use an offshore subcontractor to perform services that will receive, process, transfer, handle, store, or access protected health information (PHI) of our members in oral, written, or electronic form, must complete an [Offshore Services Attestation](#).

Examples of PHI include member name, date of birth, address, social security number, health insurance claim number, patient identifiers, medical diagnosis, medical history, treatment records, type of provider visited, use of health care services, payment information, evidence of insurance coverage, or any information that could reasonably lead to the identification of a Senior Preferred member. For example, if an FDR contracts with and provides PHI for a Quartz Medicare Advantage member to an offshore company in India, then the FDR must disclose this information in the Offshore Services Information section of Quartz’s Medicare Advantage FDR Annual Compliance Attestation and complete and submit an [Offshore Services Attestation](#).

Examples of functions that involve a FDR sharing PHI with an offshore subcontractor or offshore staff include, but is not limited to: claims processing, claim data entry services, scanning paper claims to create electronic records, receiving medical data for interpretation, receipt of member calls, IT services where access to PHI is available, and any other situation where the offshore subcontractor may have access to member PHI.

### **37. What type of auditing are FDRs required to perform for offshore subcontractors?**

FDRs are responsible for ensuring that offshore subcontractors abide by all applicable Medicare Part C, Part D, and HIPAA requirements. FDRs have the discretion to determine the audit criteria that are important for continuing a relationship with an offshore subcontractor. CMS expects FDRs to adopt audit criteria substantial enough to ensure appropriate protection of PHI. CMS suggests, but does not require, an on-site audit of offshore contractors. The purpose of an on-site audit is, to observe whether PHI is handle appropriately on a day-to-day basis. FDRs may hire third-party audit organizations to conduct audits.

**38. How often do I have to complete the Offshore Services Attestation?**

The Quartz [Medicare Advantage Offshore Services Attestation](#) is due annually each year as part of our oversight of FDRs.

**39. Who should I submit the Offshore Services Attestation to?**

You must submit your completed Quartz [Medicare Advantage Offshore Services Attestation](#) via email to [QuartzFDR@quartzbenefits.com](mailto:QuartzFDR@quartzbenefits.com) or via fax to (608) 881-8394, Attn: Compliance Department.