



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

These FAQs were developed for our FDRs. Here we provide answers about Medicare compliance program requirements. Each requirement is further explained in more detail within our [Medicare Advantage FDR Compliance Program Guide](#). FDRs can also access our [Senior Preferred FDR webpage](#) for more information.

I. FDR general questions

1. What is a First Tier, Downstream and Related Entity (FDR)?

Answer: The Centers for Medicare & Medicaid Services (CMS) defines them as follows:

- **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 MA benefit or 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** - Any entity that is related to the MAO Part D sponsor by common ownership or control and:
 1. Performs some of the MA organization or Part D plan sponsor's management functions under contract or delegation
 2. Furnishes services to Medicare enrollees under an oral or written agreement
 3. Leases real property or sells material to the MA organization or Part D plan sponsor at a cost of more than \$2,500 during a contract period.

2. What products and plans do these requirements apply to?

Answer: Our Senior Preferred product is a Medicare Advantage Prescription Drug (MAPD) benefit plan that offers Part C (medical coverage) and Part D (Prescription drug) coverage to eligible beneficiaries. These requirements apply to all our Part C and Part D Medicare products.

3. I am a Part A or Part B provider. Do compliance program requirements apply to me?

Answer: Yes, we offer Medicare Advantage (Part C) and Prescription Drug (Part D) coverage to Senior Preferred members.

4. What is the source of these requirements?

Answer: CMS requires FDRs to satisfy specific Medicare compliance program requirements. The Code of Federal Regulations (CFR) Section 422.503(b)(4)(vi)(C) and Section 423.504(b)(4)(vi)(C) outlines these regulatory requirements. They are also defined by CMS in the Compliance Program Guidelines in Section 50.3 [Chapter 21 of the Medicare Managed Care Manual](#) and [Chapter 9 of the Prescription Drug Benefit Manual](#).

5. Are the compliance program requirements new?

Answer: No, the Medicare compliance program requirements are not new. Effective January 1, 2016, CMS updated their requirements. As an FDR, you and/or your organization and all your Downstream Entities must comply with Medicare compliance program requirements. Medicare compliance program requirements include, but are not limited to:

- Completion of the CMS general compliance training and FWA training modules
- Distribution of the Code of Conduct and compliance program policies
- Office of Inspector General (OIG) and the Government Services Administration (GSA) exclusion list screenings
- Record accessibility
- Reporting of FWA and compliance concerns to Senior Preferred
- Offshore operations and CMS reporting
- Specific federal and state compliance obligations
- Monitoring and auditing of first-tier, downstream and related entities

If you are not familiar with the requirements, please read through our [Medicare Advantage FDR Compliance Program Guide](#).

6. What will happen if I don't comply with the Medicare compliance program requirements and those addressed in our provider agreement?

Answer: Noncompliance will be handled on a case-by-case basis. If areas of noncompliance are identified, we may take action against you to ensure the deficiency is corrected. Depending on the severity of the noncompliance issue, it may require retraining, development of a formal corrective action plan (CAP), increased monitoring, or termination of your contract. We are required to follow established CMS laws and regulations. This requirement is not optional for us or for our FDRs.

7. Why am I receiving a notice to complete an attestation?

Answer: If you were asked to complete a Medicare Advantage FDR Annual Compliance Attestation, then we consider you a first tier entity because of your contractual relationship with us. First tier entities must comply with the Medicare compliance program requirements. CMS requires us to have oversight of our FDRs. Part of this oversight includes obtaining verification that you understand your contractual obligations, and are complying with Medicare compliance program requirements.

8. Who is required to complete an attestation?

Answer: An authorized representative must complete and submit an attestation on behalf of your organization. We describe who an authorized representative might be on page 3 of our [Medicare Advantage FDR Compliance Program Guide](#).

9. Do I need to submit an attestation if I am deemed?

Answer: Yes, you are still required to submit a completed attestation. You must attest to compliance with all the Medicare compliance program requirements.

10. How often do I have to complete the Compliance Attestation?

Answer: The Medicare Advantage FDR Annual Compliance Attestation is due annually each year as part of our oversight of FDRs.

11. Who should I submit the Annual Compliance Attestation to?

Answer: Please submit your completed attestation email to SeniorPreferred.FDR@Quartzbenefits.com; or via fax at (608) 881-8394, Attn: Tina Shuda, Compliance Department.

12. Who do I contact if I have questions regarding this FAQ or requirements for FDRs?

Answer: Questions can be sent to SeniorPreferred.FDR@QuartzBenefits.com

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

Answer: 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.

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

14. Why is it necessary for our organization to provide general compliance and FWA training to FDRs and their and downstream entities and related entities?

Answer: CMS requires MAOs and Part D sponsors to ensure general compliance and FWA training and education is provided to their FDRs and that FDRs provide training to their employees as well as downstream and related entities.

15. Do we need to use CMS' training?

Answer: Yes. Effective January 1, 2016, CMS requires all FDRs complete CMS' training modules:

- [Combating Medicare Parts C and D Fraud, Waste and Abuse Training](#)
- [Medicare Parts C and D General Compliance Training](#)

- Your applicable employees and downstream entities can access the training on CMS' Medicare Learning Network (MLN), or content of such training at: [Medicare Learning Network \(MLN\)](#).
- You can also download or print the training modules and incorporate them into your existing training materials. Please note, the content of CMS training modules cannot be modified to ensure reliability and completeness of the training. CMS will allow modifications only to the appearance of the content (e.g. font, color, background, format, etc.)
- You can also access CMS's training modules listed above on Senior Preferred's webpage at [FDRs CMS Compliance Program Requirements](#)

You must retain records to show your employees have completed the training. You can use attestations, training logs or other documents as evidence, and keep records for at least 10 years.

16. How often do the trainings have to be completed?

Answer: CMS training modules must be completed within 90 days of hire or contracting and annually thereafter.

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

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

- Attendance sheets
- Certificates of completion/attestations
- Training logs/sign-in sheets
- Electronic acknowledgements

Keep records of these for a minimum of 10 years. Senior Preferred and CMS 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.

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

Answer: Only FWA training (*Combating Medicare Parts C and D Fraud, Waste and Abuse Training*) 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 (*Medicare Parts C and D General Compliance Training*) and meet other CMS compliance program requirements found on page 3 of our [Medicare Advantage FDR Compliance Program Guide](#).

III. Code of Conduct and compliance policies

19. What is a Code of Conduct?

Answer: A Code of Conduct also know as the “Standards of Conduct,” is the all-encompassing principles and values by which the company operates, and defines the structure of the compliance program.

20. How often must the Code of Conduct be distributed?

Answer: The Code of Conduct and/or compliance policies must be distributed to employees annually, within 90 days of hire, and when changes are made. FDRs can disseminate Senior Preferred’s [Code of Conduct](#) and [applicable compliance program policies](#)

21. Can I use my own Code of Conduct?

Answer: Yes, you can use a comparable Code of Conduct and compliance policies. If you don’t have a Code of Conduct or compliance policies, use Senior Preferred’s Code of Conduct and applicable compliance program policies. You can also access Senior Preferred’s Code of Conduct and applicable compliance program policies on [Senior Preferred’s FDR webpage](#) under “Resources.”

IV. Exclusion lists screenings

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

Answer: There are two exclusion lists FDRs must check:

- OIG List of Excluded Individuals and Entities (LEIE) at <http://oig.hhs.gov/exclusions/index.asp>
- GSA System for Award Management (SAM) at www.sam.gov

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

Answer: The OIG LEIE contains the exclusion actions taken by the OIG, and SAM includes exclusions and debarment actions taken by various federal agencies.

24. Who must we verify is not excluded or debarred from participation in Medicare?

Answer: All employees, temporary employees, volunteers, contracted employees, consultants, governing board members, contractors, that will be involved in, or have access to, any information related to the FDR’s contract with us.

25. What are the requirements related to exclusion list screenings?

Answer: FDRs must review the OIG and GSA exclusion list prior to hire/contracting and monthly thereafter. Screening at the same time or “upon hire” does not meet the requirement. CMS prohibits us from employing or contracting with any individual or entity that is excluded or debarred from participating in federal health care programs. This same requirement extends to Senior Preferred’s FDRs and the FDRs downstream and related entities. We explain this requirement on pages 6 and 7 of the [Medicare Advantage FDR Compliance Program Guide](#).

26. How often do the exclusion and debarment checks need to be completed?

Answer: The OIG and GSA exclusion lists must be checked initially before hire/contract execution and monthly thereafter.

Medicare payment may not be made for items or services furnished or prescribed by an excluded provider or entity. Senior Preferred shall not use federal funds to pay for services, equipment or drugs prescribed or provided by a provider, supplier, employee or FDR excluded by OIG or GSA. Monthly screening is essential 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.

27. Do I need to maintain evidence/documentation to show these checks were completed?

Answer: Yes. Evidence of exclusion/debarment verification depends on the system used to conduct these screenings. Some FDRs use an automated system that screens both OIG and GSA websites, while others go directly to the website to verify exclusion/debarment. Regardless of the system or process you use, you must maintain documentation that demonstrates fulfillment of your obligation to verify exclusions/debarment for at least 10 years. Such evidence may include screen prints of the exclusion results, exclusion reports, etc. The evidence must clearly show:

- The name of the individual or entity checked;
- What exclusion/debarment list was checked;
- The date the source was verified;
- The result of the check; and
- Any action taken if sanctioned individuals or entities were identified.

28. What should I do if an individual or entity shows up as excluded or debarred?

Answer: The individual or entity must be immediately removed from directly or indirectly servicing or accessing Senior Preferred's Medicare Advantage product. You must also report this finding immediately to us. Reporting resources can be found on page 7 of the [Medicare Advantage FDR Compliance Program Guide](#).

V. Record Retention

29. How long do I need to maintain records?

Answer: CMS requires FDRs to maintain records of Medicare compliance program requirements. Examples include: employee training records, distribution of the Code of Conduct or compliance policies, and exclusion list screenings, for a minimum of 10 years. You can access our Documentation Retention Policy [here](#).

We may ask you to provide documentation of your compliance with Medicare compliance program requirements. An FDR's inability to produce documentation may result in a request for corrective action or other contractual remedies.

VI. Reporting Mechanisms

30. Do we have to report noncompliance and FWA to Senior Preferred?

Answer: Yes, issues that impact Senior Preferred's Medicare Advantage business must be reported to promptly. FDRs should train employees on the importance of reporting violations of noncompliance and FWA. As an FDR that contracts with the Senior Preferred, you must ensure all your employees and those of any of your downstream and related entities are informed of how to report compliance concerns and suspected misconduct.

Reporting is critical for the prevention, detection, and correction of fraud, waste and abuse. Our [Compliance Reporting Poster](#) can be used to post in your organization and can be distributed to downstream or related entities to advise them how to report Medicare program compliance concerns and/or FWA to us without fear of intimidation or retaliation against anyone who reports a concern in good faith.

VII. Validation/Audit of Effective Compliance Program Requirements

31. What documentation/evidence will we or CMS ask FDRs for to support their compliance with Medicare compliance requirements?

Answer: A variety of information could be requested by us and/or CMS. Please reference our [Evidence Examples](#) table that provides examples of the types of evidence that may be requested.

32. Why are we asking for all this information?

Answer: CMS requires that we conduct oversight of contracted entities to ensure they are meeting CMS compliance expectations for all Part C & D related responsibilities. FDRs are required to provide documentation at the request of Senior Preferred and/or CMS.

VIII. Downstream entity oversight

33. Why are we asking about downstream entities (i.e. subcontractors)?

Answer: 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. You must obtain an attestation from your downstream entities to monitor their compliance with Medicare compliance program requirements.

34. What requirements apply to downstream entities?

Answer: Downstream entities must comply with applicable regulatory and sub 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](#).

35. What oversight is expected for my subcontractors?

Answer: CMS requires FDRs and any of their downstream and related entities maintain compliance of all CMS compliance program requirements, as applicable, while servicing Senior Preferred Medicare Advantage products. This includes the compliance program requirements already mentioned, as well as any others that may apply that are not listed in these FAQs. For example, CMS requires the reporting and oversight of any and all entities that manage PHI offshore. Therefore, it is expected that you identify any such services for your own organization or any of your downstream/related entities in order to conduct oversight of those processes and report them to us. If you use downstream and/or related entities for Senior Preferred's Medicare Advantage products, you must ensure that proper oversight is conducted for all CMS requirements through ongoing monitoring processes and annual audits.

IX. Offshore Subcontractors

36. What is an offshore subcontractor?

Answer: 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.

37. 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 Senior Preferred?

Answer: 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 Subcontractor 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 a FDR contracts with and provides PHI for a Senior Preferred member to an offshore company in India, then the FDR must disclose this information in the Offshore Subcontractor Reporting section of Senior Preferred’s Medicare Advantage FDR Annual Compliance Attestation and complete and submit an [Offshore Subcontract 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.

38. What type of auditing are FDRs required to perform for offshore subcontractors?

Answer: 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.

39. How often do I have to complete the Offshore Subcontractor Attestation?

Answer: A Medicare Advantage FDR Annual Compliance Attestation is due annually each year as part of our oversight of FDRs.

40. Who should I submit the Offshore Subcontractor Attestation to?

Answer: Please submit your completed Offshore Subcontractor Attestation via email to SeniorPreferred.FDR@QuartzBenefits.com; or via fax to (608) 881-8394, Attn: Tina Shuda, Compliance Department.