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 does FDR mean?  
   **Answer:** FDR stands for first tier, downstream and related entities. If you perform an administrative or health care service function on behalf of Senior Preferred’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, 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 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** – 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 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; or
     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, plans, and providers 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 provider for Original Medicare (Parts A or B). Do compliance program requirements apply to me?  
   **Answer:** If you are a provider that accepts Original Medicare (Part A and B) and contracts with Senior Preferred 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 Senior Preferred, please contact us at SeniorPreferred.FDR@quartzbenefits.com.

4. What is the source of these requirements?
   Answer: These regulatory requirements are from CMS. CMS requires FDRs to satisfy specific Medicare compliance program requirements. They are described within The Code of Federal Regulations (CFR) Section 422.503(b)(4)(vi)(C) and Section 423.504(b)(4)(vi)(C) and Chapter 21 of the Medicare Managed Care Manual and Chapter 9 of the Prescription Drug Benefit Manual.

5. Are the requirements new?
   Answer: No, these 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. There have been changes to these requirements since they were implemented. Medicare compliance program requirements include, but are not limited to:
   - Completion of general compliance and FWA training
   - Distribution of the Code of Conduct and compliance program policies
   - Office of Inspector General (OIG) and the Government Services Administration (GSA) exclusion list screening
   - Record retention
   - Reporting of FWA and compliance concerns to Senior Preferred
   - Offshore operations and CMS reporting
   - Specific federal and state compliance obligations
   - Monitoring and auditing of downstream 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? Who do we report this to? Will we be terminated?
   Answer: If you are not meeting the requirements, we will partner with you to resolve the issue. You will be provided training and education on the requirements and we will make sure that you develop a detailed corrective action plan (CAP). We will ask that you provide a written CAP that addresses the issue and outlines when actions will be completed.

   Noncompliance will be handled on a case-by-case basis. If you are willing to comply with the requirements, your contract will not be terminated. If you refuse to comply or fail to implement your CAP, there could be ramifications, up to and including contract information. 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 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 an attestation to confirm that you understand and are complying with Medicare compliance program requirements.

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8. Who is required to complete the attestation?
   Answer: An authorized representative must complete and submit an attestation on behalf of your organization. We describe who might be 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.

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?
    Answer: If you have questions about the Medicare compliance requirements that are not addressed in our Medicare Advantage FDR Compliance Program Guide, you can submit your questions 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?
    Answer: CMS expects MAOs and Part D sponsors to provide general compliance and FWA training to their FDRs, and that FDRs provide training to their employees as well as downstream entities.

15. Do we need to use CMS' training?
    Answer: No. CMS enacted a Final Rule effective June 15, 2018. This rule removes the requirement for FDRs to complete CMS-issued general compliance and FWA training beginning in 2019.

    However, as a first tier entity, you must provide general compliance and FWA training to employees and downstream entities assigned to provide administrative and/or health care services for Senior Preferred’s Medicare Advantage business. FDRs can find the training requirements in the Medicare Managed Care Manual Ch. 21 §§50.3.1 and 50.3.2. To comply with this requirement, you may:
    1. Complete the trainings provided on the CMS Medicare Learning Network (MLN) website. The general compliance training is called Medicare Parts C and D General Compliance Training, and the FWA training is called Combating Medicare Parts C and D Fraud, Waste, and Abuse Training.
    2. You can download or print the contents of the CMS trainings from the CMS MLN website and incorporate them into your existing training materials.
    3. Complete the CMS Medicare Parts C and D training modules listed above on Senior Preferred’s webpage at FDRs CMS Compliance Program Requirements.
    4. Complete your organizations developed general compliance and FWA training.
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:** Trainings 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 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 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:
   - Within 90 days of hire;
   - When changes are made; or
   - Annually

21. **Can I use my own Code of Conduct?**
   **Answer:** 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 Senior Preferred’s [Code of Conduct](#) and [applicable compliance program policies](#).
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:  
   - Office of Inspector General (OIG) List of Excluded Individuals and Entities (LEIE)  
   - General Services Administration (GSA) System for Award Management (SAM)

23. What is the difference between the OIG LEIE and GSA SAM?  
   Answer: The OIG only contains the exclusion actions taken by the OIG, and GSA SAM includes exclusion 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 both the OIG and GSA SAM exclusion list 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 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. 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.

26. How often do the exclusion and debarment checks need to be completed?  
   Answer: Both the OIG and GSA SAM exclusion lists must be checked before hiring/contracting and monthly thereafter.

27. What evidence/documentation must I keep to show checks were completed?  
   Answer: The evidence of exclusion verification depends on how you complete screenings and the system used to conduct these screenings. If you use 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, your documentation must demonstrate 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:  
   - Which exclusion list(s) were checked  
   - Name of the individuals or entities checked;  
   - Date the check was completed;  
   - Results of the check; and  
   - Action taken if sanctioned individuals or entities were identified.

28. What should I do if an individual or entity is identified as excluded?  
   Answer: You should immediately stop them from doing any work on Senior Preferred’s Medicare Advantage business. You must also report this finding immediately to Senior Preferred. Reporting resources can be in the Medicare Advantage FDR Compliance Program Guide.

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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. 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.

31. Do we have to report noncompliance and FWA to Senior Preferred?
   Answer: Yes. Your internal processes must include a process to report concerns to Senior Preferred. You should train your employees on the importance of reporting violations of noncompliance and FWA. As an FDR that contracts with the Senior Preferred, you must notify Senior Preferred about any actual or potential noncompliance and FWA if it impacts our Medicare Advantage business.

   Reporting is critical for the prevention, detection, and correction of fraud, waste and abuse. If you don’t have internal reporting mechanisms, you can share our Compliance Reporting Poster with your employees and downstream entities so they can report things directly without fear of intimidation or retaliation against anyone who reports a concern in good faith.

32. What can I do if I suspect FWA or noncompliance?
   Answer: You must report the issue to us so we can investigate and respond to it immediately. Our Compliance Reporting Poster describes a few of the ways you can make reports.

   As a Senior Preferred FDR, you can make reports using any of the mechanisms listed in the Code of Conduct. Don’t worry about retaliation. We enforce a zero-tolerance policy for retaliation against anyone who reports suspected misconduct.

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VII. Validation/Audit of Effective Compliance Program Requirements

33. 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.

34. 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

35. Which of my subcontractors should be considered downstream entities?
   **Answer:** Not every subcontractor is considered a Downstream Entity. Only those who provide administrative or health care services for Senior Preferred’s Medicare Advantage business are Downstream Entities. FDRs should have processes in place to identify and classify subcontractors as Downstream Entities.

36. Why are we asking about my 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.

37. 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.

38. What oversight is expected for my downstream entities?
   **Answer:** If you utilize downstream entities you must have acceptable oversight of their compliance and performance. 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

39. 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 Mariana Islands, 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.

40. 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 Subcontractor 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.

41. 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.
42. 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.

43. 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.