

**ATTACHMENT I-D**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM**  
**EFFECTIVENESS (CPE)**  
**SPONSOR'S ACCOUNTABILITY FOR AND OVERSIGHT OF FIRST-TIER,**  
**DOWNSTREAM AND RELATED ENTITIES QUESTIONNAIRE (FDR-Q)**

(Rev. 2. 10-2016)

**Name of Sponsoring Organization:**

**MA-PD/PDP Contract Numbers:**

**Name and Title of Person Completing Questionnaire:**

**Date of Completion:**

**Directions for Completing the FDR Oversight Questionnaire:**

This questionnaire will assist CMS with understanding the sponsoring organization's accountabilities and oversight of its delegated entities to ensure their compliance with Medicare program requirements.

The responses to these questions may be discussed during the onsite portion of the CPE audit.

We recognize that your time is valuable and appreciate your availability to provide responses to our questions regarding the compliance program.

If multiple individuals are responsible for the operations and oversight of first-tier, downstream and related entities (e.g. Corporate Compliance Officer, Delegated Entity Compliance Officer, Vendor Management Group, etc.) and have different responses to the questions, please consolidate responses and incorporate into one document.

Please specifically note the following when completing the questionnaire:

- "You" refers to your organization, not necessarily a specific person.
- "Employees" refer to employees, including senior management, who support your Medicare business.
- "Compliance Officer" refers to the compliance officer who oversees the Medicare business.
- "CEO" refers to the Chief Executive Officer of the organization or the most senior officer, usually the President or Senior Vice President of the Medicare line of business.
- "Compliance Program" refers to your Medicare compliance program.
- If the Medicare contract holder is a wholly owned subsidiary of a parent company, references to the governing body, CEO and highest level of the organization's management are to the board, CEO and management of the company (parent or subsidiary/contract holder) that the organization has chosen to oversee its Medicare compliance program.
- "FDRs" refer to the organization's first-tier, downstream and related entities contracted to perform an administrative or healthcare service to enrollees on behalf of the Sponsor.

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- “First Tier Entity” refers to any party that enters into a written agreement, acceptable to CMS, with an MAO or Part D plan sponsor or applicant to provide administrative services or health care services to a Medicare eligible individual under the MA program or Part D program.
- “Downstream Entity” refers to any party that enters into a written agreement, acceptable to CMS, with persons or entities involved with the 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 agreements continue down to the level of the ultimate provider of both health and administrative services.
- “Related Entity” 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 materials to the MAO or Part D plan sponsor at a cost of more than \$2,500 during a contract period.
- If the Medicare contract holder is a wholly owned subsidiary of a parent company, references to the governing body, CEO and highest level of the organization’s management are to the governing body, CEO and management of the company (parent or subsidiary/contract holder) that the organization has chosen to oversee its Medicare compliance program.

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1. How long have you been employed with the sponsor and been involved with overseeing FDRs?

2. Have you held any positions in the company, prior to being the person or a part of the team responsible for managing delegated entities?

3. Are delegated entities managed by one individual or a group of individuals/departments?

4. Provide a general overview of the delegated entity oversight program.

5. The method by which the analysis for determining whether a contracted entity is categorized as a FDR according to CMS' definitions is left to the discretion of the sponsoring organization. Please describe your criteria for determining which delegated entities are properly identified as FDRs subject to Medicare compliance requirements.

6. How many first-tier entities does your organization contract with to perform Medicare Parts C/D functions?

7. Who or which business operations are involved with the pre-contractual assessment to ensure contractual and regulatory obligations are met.

8. Once the contract has been initiated with the delegated entity, who or which business operations are responsible for tracking and monitoring the FDRs performance and day to day oversight for compliance issues?

9. Describe the mechanisms used for oversight activities (e.g. structure, risk assessment, specialized teams focused on specific functions, etc.)

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10. Describe specific examples of the types of communications that exist between the Compliance Department and FDR Oversight regarding Medicare requirements, policy updates, performance concerns or issues with FDRs, specifically the first-tier entities such as your PBM, enrollment/membership functions, coverage or claims adjudication, network management, etc.?

11. How do you ensure that any compliance issues involving a FDR is communicated to the appropriate governance level (e.g. compliance committee, senior managers, Board of Directors, and/or the CEO)? Please provide a recent example/scenario.

12. What ongoing processes do you have to evaluate and assess the effectiveness of the delegation oversight program, such as a self-assessment tool, delegation compliance committee, scorecard, etc.?

13. How do you share information or train FDRs on your organization's culture, compliance and productivity expectations, CMS regulations, and policy for the Medicare function performed on the sponsoring organization's behalf?

14. Describe the training, education and communication program for FDRs (e.g. roles and responsibilities, compliance and FWA training, job-specific, exchange of information, compliance disclosures and failures, etc.).

15. Provide examples of the types of periodic monitoring reports your organization receives from FDRs?

16. Describe the strategy for monitoring and auditing your first tier entities for compliance regulatory requirements, downstream oversight, and implementation of corrective actions.

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17. What happens if a FDR fails to satisfactorily implement a corrective action plan or commits a serious act of noncompliance with Medicare requirement that affects enrollees from receiving their health care or drug benefit appropriately or timely?

18. What are a few of the challenges or issues with effectively overseeing FDRs your organization has experienced within the audit review period (e.g., PBM, sales brokers, entities with direct member contact, provider networks, etc.).

19. List a few of your accomplishments for FDR oversight during the audit review period? What are your priorities for delegation for the next two years?

20. Would you like to share any best practices that may assist others with succeeding in this complex area of overseeing and being accountable for FDRs' compliance with CMS regulatory requirements?

21. Do you have any comments or questions for CMS?