Program Audit Data Request
Compliance Program Effectiveness (CPE)
Compliance Oversight Questionnaire

Name of Sponsoring Organization:
Enter name here.

Contract Numbers:
Enter contract numbers here.

Name and Title of Person Completing Questionnaire:
Enter name and title here.

Date Completed:
Enter the date here.

Instructions:

This questionnaire will assist CMS with understanding the organization's compliance program and oversight of its delegated entities to ensure their compliance with Medicare program requirements. **Please upload the completed form to HPMS within 15 business days of receiving your audit engagement letter.**

This questionnaire will be submitted at the same time as the Compliance Oversight Activities universe from the CPE protocol. Your organization does not need to repeat information from that universe in the questionnaire and you can reference back to the universe if it is responsive to any of these questions.

We recognize that your time is valuable and appreciate your availability to provide responses to our questions regarding the compliance program. The responses to these questions will be discussed during the compliance interview.

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

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Please specifically note the following when completing the questionnaire:

- *"You" and "your"* 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.
- *"First Tier Entity"* refers to any party that enters into a written agreement, acceptable to CMS, with an organization to provide administrative services or healthcare services to a Medicare eligible individual under the Part C and/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 Medicare Part C and/or Part D benefits below the level of the arrangement between an organization 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 organization by common ownership or control and/or:
  - performs some of an organization's management functions under contract or delegation,
  - furnishes services to Medicare enrollees under an oral or written agreement, or
  - leases real property or sells materials to the organization 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.

CMS Questions on Compliance and Oversight:

1. How long have you been employed with the organization and served as the Medicare Compliance Officer?

2. Do you have an established method for reporting potential compliance issues, including options for anonymous and confidential reporting? If yes, please explain the method, how you disseminate information, and how your organization ensures protections for those who report in good faith.

3. Do you have a system for taking appropriate disciplinary action that includes clear expectations for reporting compliance concerns, processes for identifying and documenting noncompliance or unethical behavior, and ensures timely, consistent and effective enforcement of disciplinary standards? Please explain.

4. Please provide an overview of your compliance program and how you oversee compliance in the following program areas: Formulary Administration (FA), Part D Coverage Determinations, Appeals and Grievances (CDAG), Part C Organization Determinations, Appeals and Grievances (ODAG), and/or Special Needs Plans Coordination of Care (SNPCC)?

5. What is your process for monitoring and auditing your internal organization components that operate or perform functions in FA, CDAG, ODAG, and SNPCC and what individual/committee is primarily responsible for that oversight?

6. How many first-tier entities does your organization contract with to perform Medicare Part C and Part D functions? Please describe the functions they perform both generally and as they relate to FA, CDAG, ODAG, and SNPCC.

7. Provide an overview of how the compliance department (or other individuals/entities in your organization) oversees your first-tier, downstream and related entities.

8. Please identify individuals, committees, or entities responsible for oversight of functions delegated to first-tier, downstream and related entities, such as FA, CDAG, ODAG, and/or SNPCC functions.

9. Describe how the compliance department communicates with first-tier, downstream and related entities to ensure they are aware of Medicare requirements, policy updates, performance concerns, issues, etc.

10. What is your process for monitoring and auditing first-tier entities' compliance with requirements, downstream oversight, and implementation of corrective actions both generally and as they relate to FA, CDAG, ODAG, and SNPCC?

11. Do you monitor and/or audit all first-tier entities or do you conduct monitoring/auditing based on a risk assessment tool? If you use a risk assessment, how do you judge risk when it comes to overseeing your first-tier entities?

12. In the past 6 months, have you identified any concerns or findings with any first-tier entity, or your own internal components, related to the identified program areas (i.e., FA, CDAG, ODAG, or SNPCC)? Give a brief description of any identified concerns or, if these are noted already in your COA universe, you may point to the universe in your answer.

13. In the past 6 months, have any first-tier or internal components self-reported issues or potential noncompliance in the identified program areas? If so, please provide an overview of the types of noncompliance or issues that were identified and whether the issues represent systemic problems or repeated areas of concern.

14. Describe the methods or processes used for tracking compliance issues through resolution and remediation and to ensure root causes are addressed to prevent recurrence.

15. Briefly explain how you approach a new situation, emerging issues, or a new CMS policy, where an internal policy or process is not in place to respond to the issue or to implement new requirements.

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

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-1395 (Expires MM/DD/CCYY). This is a mandatory information collection. The time required to complete this information collection is estimated to average 390 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. ****CMS Disclosure**** Please do not send applications, claims, payments, medical records, or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact part_c_part_d_audit@cms.hhs.gov.