

ATTACHMENT V
MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS
SELF-ASSESSMENT QUESTIONNAIRE

(Rev. 3, 12-2012)

Name of Sponsoring Organization: _____

MA-PD/PDP Contract Numbers: _____

Name/Title of Person Completing Assessment: _____

Date of Assessment: _____

Note: Sponsoring Organizations should not interpret every question as a mandatory CMS requirement, but rather as a guide in evaluating the effectiveness of their Compliance Program.

Directions for completing the self-assessment questionnaire:

This document will help your organization evaluate the effectiveness of your Medicare Compliance Program. Please respond to each question according to the current status of your Compliance Program. If the answer is “YES” to any question below, check the “YES” box and provide a **BRIEF** description of what documents support that response in the “Documentation” column. The Documentation description should also provide a cross reference (when applicable) to where this documentation can be located. For example, if your response is “YES” to the third question below (“*Do your written Ps & Ps and/or Standards of Conduct articulate the organization’s commitment to comply with all applicable Federal and State standards including but not limited to statutes, regulations and sub regulatory guidance*”), please indicate the section/page of the Standards of Conduct or policies and procedures where these compliance provisions are found.

If the answer is “NO” to a question, check the “NO” box and document the rationale for the response in the “Documentation” column.

Please specifically note the following when completing the questionnaire:

- “You” refer to your organization, not necessarily a specific person.
- “Employees” refers to employees, including senior management, who support your Medicare business.
- “Compliance Officer” refers to the compliance officer who oversees the Medicare business.

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- “CEO” refers to Chief Operating Officer of the organization or the most senior officer, usually the President.
- “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 board of directors, 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. .
- Unless specific reference is made in the question to the “full board”, the term “board of directors” means either the full board or a committee of the board delegated to conduct oversight of the day-to-day operation of the Medicare compliance program on behalf of the full board.

Element I: Written Policies and Procedures and Standards of Conduct

42 CFR §422.503(b)(4)(vi)(A) and 42 CFR §423.504(b)(4)(vi)(A)

	Description	Yes	No	Documentation	Responsible Party or Department
1.	Do you have written policies and procedures (Ps & Ps) and/or Standards of Conduct that:				
A.	Articulate the organization’s commitment to comply with all applicable Federal and State standards?				
B.	Describe compliance expectations as embodied in the standards of conduct?				
C.	Implement the operation of the compliance program?				

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Element I: Written Policies and Procedures and Standards of Conduct

42 CFR §422.503(b)(4)(vi)(A) and 42 CFR §423.504(b)(4)(vi)(A)

	Description	Yes	No	Documentation	Responsible Party or Department
D.	Provide guidance to employees and others on dealing with potential compliance issues?				
E.	Identify how to communicate compliance issues to appropriate compliance personnel?				
F.	Describe how potential compliance issues are investigated and resolved by the organization?				
G.	Include a policy of non-intimidation and no-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials?				
2.	Are your Ps & Ps detailed and specific in their description of the operation of the compliance program?				

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Element I: Written Policies and Procedures and Standards of Conduct

42 CFR §422.503(b)(4)(vi)(A) and 42 CFR §423.504(b)(4)(vi)(A)

	Description	Yes	No	Documentation	Responsible Party or Department
3.	Do you distribute your Standards of Conduct and Ps & Ps to your employees within 90 days of hire, when there are updates and annually thereafter?				
4.	Do you update your Ps & Ps to incorporate changes in applicable laws, regulations and other program requirements?				

Element II: Compliance Officer, Compliance Committee, Governing Body

42 CFR §422.503(b)(4)(vi)(B) and 42 CFR §423.504(b)(4)(vi)(B)

	Description	Yes	No	Documentation	Responsible Party or Department
5.	Does your CEO receive your compliance officer's reports on the status and activities of the compliance program?				

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Element II: Compliance Officer, Compliance Committee, Governing Body

42 CFR §422.503(b)(4)(vi)(B) and 42 CFR §423.504(b)(4)(vi)(B)

	Description	Yes	No	Documentation	Responsible Party or Department
6.	If your compliance officer does not report directly, in-person to your CEO, are his/her reports routed through the President of the division that houses the Medicare and/or through the President of the organization rather than through operational management?				
7.	Does your compliance officer have express authority (oral or written, preferably written) to make in-person reports to your CEO and Board of Directors in the compliance officer's sole discretion?				
8.	Is your compliance officer employed by your organization, parent organization, or corporate affiliate?				
9.	If employed by your parent or corporate affiliate, does your compliance officer have detailed involvement in and familiarity with your Medicare operational and compliance activities?				

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Element II: Compliance Officer, Compliance Committee, Governing Body

42 CFR §422.503(b)(4)(vi)(B) and 42 CFR §423.504(b)(4)(vi)(B)

	Description	Yes	No	Documentation	Responsible Party or Department
10.	Does your Board of Directors periodically receive compliance reports on Medicare program noncompliance and Medicare fraud, waste and abuse (“FWA”) which include issues identified, investigated, and resolved?				
11.	If your compliance officer does not report in-person to your Board of Directors, are his/her reports routed through the compliance infrastructure?				
12.	Is your compliance officer a full-time employee?				
13.	Does your compliance officer have both compliance and operational responsibilities?				
14.	Do you have a compliance committee whose responsibilities include oversight of the compliance program?				

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Element II: Compliance Officer, Compliance Committee, Governing Body

42 CFR §422.503(b)(4)(vi)(B) and 42 CFR §423.504(b)(4)(vi)(B)

	Description	Yes	No	Documentation	Responsible Party or Department
15.	Does your compliance officer and compliance committee provide the Board of Directors with regularly scheduled updates on the status and activities of the compliance program, including compliance program outcomes, the results of internal and external audits and about all government compliance enforcement activity?				

Element III: Effective Training and Education

42 CFR §422.503(b)(4)(vi)(C) and 42 CFR §423.504(b)(4)(vi)(C)

	Description	Yes	No	Documentation	Responsible Party or Department
16.	Do you establish, implement and provide effective training and education, addressing compliance and FWA for your employees, including temporary employees, volunteers and Board of Directors?				

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Element III: Effective Training and Education

42 CFR §422.503(b)(4)(vi)(C) and 42 CFR §423.504(b)(4)(vi)(C)

	Description	Yes	No	Documentation	Responsible Party or Department
17.	Is your training for employees and board members provided within 90 days of hire/appointment and annually thereafter?				
18.	Do you maintain attendance, topic, certificates of completion and/or test scores for 10 years?				
19.	Do you ensure that your employees are aware of Medicare requirements related to their job functions?				
20.	Does your general compliance education include the reporting requirements and available methods for reporting noncompliance and potential FWA?				
21.	Do you provide training on FWA risks based on the individual's job function?				

Element IV: Effective Lines of Communication

42 CFR §422.503(b)(4)(vi)(D) and 42 CFR §423.504(b)(4)(vi)(D)

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	Description	Yes	No	Documentation	Responsible Party or Department
22.	Do you have an effective method(s) to communicate information from your compliance officer to others, within a reasonable time frame, including changes in laws, regulations and sub-regulatory guidance as well as changes to your Standards of Conduct and Ps & Ps?				
23.	Do your Standards of Conduct and/or Ps & Ps require your employees and members of the Board of Directors to report compliance concerns and potential FWA?				
24.	Do you have a system to receive, record, respond to and track compliance questions or concerns and reports of potential FWA from your employees, members of your Board of Directors, FDRs and their employees and enrollees?				
25.	Does your system allow anonymous reporting and maintain confidentiality to the extent possible?				

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Element IV: Effective Lines of Communication

42 CFR §422.503(b)(4)(vi)(D) and 42 CFR §423.504(b)(4)(vi)(D)

	Description	Yes	No	Documentation	Responsible Party or Department
26.	Does your system emphasize your policy of non-retaliation and that of your FDRs'?				
27.	Is your system well-publicized throughout your facilities and those of your FDRs?				
28.	Are your reporting mechanisms user-friendly, easy to access and navigate and available 24 hours a day for employees, members of your Board of Directors and FDRs?				
29.	Have you adopted, widely publicized and enforced a no-tolerance policy for retaliation or retribution against any employee, FDR, or FDR employee who reports potential FWA?				
30.	Do you educate your enrollees about the identification and reporting of FWA?				

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Element V: Enforcement of Well-Publicized Disciplinary Standards

42 CFR §422.503(b)(4)(vi)(E) and 42 CFR §423.504(b)(4)(vi)(E)

	Description	Yes	No	Documentation	Responsible Party or Department
31.	Have you established and implemented disciplinary policies and procedures that reflect clear, specific disciplinary standards?				
32.	Do your disciplinary policies:				
A.	Describe your expectations for reporting compliance issues including noncompliant, unethical or illegal conduct?				
B.	State that employees must participate in required training?				
C.	State the expectations for assisting in the resolution of reported compliance issues?				
D.	Identify noncompliant, unethical or illegal behavior through examples of violative conduct that employees might encounter in their jobs?				

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Element V: Enforcement of Well-Publicized Disciplinary Standards

42 CFR §422.503(b)(4)(vi)(E) and 42 CFR §423.504(b)(4)(vi)(E)

	Description	Yes	No	Documentation	Responsible Party or Department
E.	Provide for timely, consistent and effective enforcement of the standards?				
F.	Require disciplinary action that is appropriate to the seriousness of the violation?				
33.	Do you widely publicize disciplinary standards to your employees and FDRs?				
34.	Do you maintain disciplinary records for ten years that capture the dates of the violation and the investigation, a summary of the findings, the disciplinary action taken and the date it was taken?				

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Element VI: Effective System for Routine Monitoring, Auditing, and Identification of Compliance Risks

42 CFR §422.503(b)(4)(vi)(F) and 42 CFR §423.504(b)(4)(vi)(F)

	Description	Yes	No	Documentation	Responsible Party or Department
35.	Do you have a system of ongoing monitoring and auditing to test and confirm compliance with Medicare regulations, sub-regulatory guidance, contractual agreements and all applicable federal and state laws?				
36.	Are adequate resources devoted to your audit function considering the scope of your Parts C and D programs, compliance history, current compliance risks and resources available?				
37.	Do you have a monitoring and auditing work plan that addresses risks associated with Medicare Parts C and D?				
38.	Does your compliance officer receive regular reports from those who are conducting the auditing or the audit department on the results of auditing and monitoring and on the status and effectiveness of corrective actions taken?				

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Element VI: Effective System for Routine Monitoring, Auditing, and Identification of Compliance Risks

42 CFR §422.503(b)(4)(vi)(F) and 42 CFR §423.504(b)(4)(vi)(F)

	Description	Yes	No	Documentation	Responsible Party or Department
39.	Does your compliance officer or his/her designee provide updates on the results of monitoring and auditing to your compliance committee, CEO, senior leadership and Board of Directors?				
40.	Have you established and implemented Ps & Ps to conduct a formal baseline risk assessment of the major compliance and risk areas in all Medicare operational areas?				
41.	Does your monitoring and auditing strategy prioritize (a) risks identified through CMS audits and oversight and through your own monitoring; and (b) those risks that have the greatest impact?				
42.	Do you periodically re-evaluate the accuracy of your baseline risk assessment?				
43.	Do you have an auditing and monitoring work plan that includes:				

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Element VI: Effective System for Routine Monitoring, Auditing, and Identification of Compliance Risks

42 CFR §422.503(b)(4)(vi)(F) and 42 CFR §423.504(b)(4)(vi)(F)

	Description	Yes	No	Documentation	Responsible Party or Department
A.	A process for responding to all monitoring and auditing results?				
B.	A process for conducting follow-up reviews of areas found to be noncompliant to determine if corrective actions have fully address the underlying problems?				
C.	A schedule that lists all auditing and monitoring activities for the calendar year?				
44.	Do you use appropriate methods to:				
A.	Select operational areas for audit?				
B.	Select first tier entities for audit?				
C.	Determine sample size?				
D.	Extrapolate audit findings to the full universe, using statistically valid methods that comply with generally accepted auditing standards?				

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Element VI: Effective System for Routine Monitoring, Auditing, and Identification of Compliance Risks

42 CFR §422.503(b)(4)(vi)(F) and 42 CFR §423.504(b)(4)(vi)(F)

	Description	Yes	No	Documentation	Responsible Party or Department
E.	Apply specialized targeted techniques or stratified sampling methods driven by data mining, complaint monitoring and aberrant behavior?				
F.	Assess compliance with internal processes and procedures?				
45.	Do you have staff dedicated to the audit function?				
A.	Are your auditors Knowledgeable about CMS operational requirements for areas under review, independent and not engaged in self-policing?				
46.	Does your audit staff have access to relevant personnel, information, records and areas of operation under review, including operational areas at plan and FDR level?				
47.	Do you audit the effectiveness of your compliance program at least annually?				

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Element VI: Effective System for Routine Monitoring, Auditing, and Identification of Compliance Risks

42 CFR §422.503(b)(4)(vi)(F) and 42 CFR §423.504(b)(4)(vi)(F)

	Description	Yes	No	Documentation	Responsible Party or Department
48.	Is the audit conducted by persons other than your compliance officer and/or compliance department staff?				
49.	Do you share the results of the audits of the effectiveness of the compliance program with your Board of Directors?				
50.	Do you review the OIG and GSA exclusion lists for your employees (including temporary employees), volunteers, consultants and the members of your board of directors prior to hiring/contracting/appointment and monthly thereafter?				
51.	Do you utilize data analysis for monitoring for FWA?				
52.	Do you either have a Special Investigations Unit (“SIU”) or ensure that the responsibilities generally conducted by an SIU are conducted by your compliance department?				

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Element VI: Effective System for Routine Monitoring, Auditing, and Identification of Compliance Risks

42 CFR §422.503(b)(4)(vi)(F) and 42 CFR §423.504(b)(4)(vi)(F)

	Description	Yes	No	Documentation	Responsible Party or Department
53.	If you have an SIU, is it accessible through multiple channels, e.g. phone, mail, Internet message?				
54.	Do your SIU and compliance departments communicate and coordinate closely?				

Element VII: Procedures and Systems for Promptly Responding to Compliance Issues

42 CFR §422.503(b)(4)(vi)(G) and 42 CFR §423.504(b)(4)(vi)(G)

	Description	Yes	No	Documentation	Responsible Party or Department
55.	Do you make a reasonable inquiry into all compliance incidents/issues and potential FWA?				
56.	Do you require and ensure that your inquiries are well-documented?				

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Element VII: Procedures and Systems for Promptly Responding to Compliance Issues

42 CFR §422.503(b)(4)(vi)(G) and 42 CFR §423.504(b)(4)(vi)(G)

	Description	Yes	No	Documentation	Responsible Party or Department
57.	Do you require and ensure that inquiries are initiated as quickly as possible and not later than two weeks after the date the potential noncompliance or FWA is identified?				
58.	Do you undertake appropriate corrective actions that:				
A.	Are designed to correct and prevent future noncompliance, including conducting a root cause analysis?				
B.	Are tailored to address the particular FWA, problem or deficiency identified?				
C.	Include time frames for specific achievements?				
59.	Do you continue to monitor corrective actions after their implementation to ensure that they are effective?				

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Element VII: Procedures and Systems for Promptly Responding to Compliance Issues

42 CFR §422.503(b)(4)(vi)(G) and 42 CFR §423.504(b)(4)(vi)(G)

	Description	Yes	No	Documentation	Responsible Party or Department
A.	Do you ensure that noncompliance or FWA committed by your employees is documented and includes ramifications should the employee fail to satisfactorily implement the corrective action?				
60.	Do you maintain thorough documentation of all compliance deficiencies identified and the corrective actions taken?				
61.	Do you have procedures to refer potential FWA issues to the NBI MEDIC and serious issues of program noncompliance to CMS?				
62.	Do you conclude your investigations of FWA within a reasonable time after the activity is discovered?				
63.	Do you review past paid claims from entities identified in fraud alerts and remove them from their event data submissions e.g. PDEs?				

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FDR Oversight

Sponsor Accountability for and Oversight of FDRs

42 CFR §422.503(b)(4)(vi) and 42 CFR §423.504(b)(4)(vi)

	Description	Yes	No	Documentation	Responsible Party or Department
64.	Do you have a process for determining which delegated entities are properly identified as FDRs subject to Medicare compliance requirements?				
65.	Do you have a system to monitor FDRs' compliance with Medicare program requirements?				

	Element I: Written Policies and Procedures and Standards of Conduct				
	<i>42 CFR §422.503(b)(4)(vi)(A) and 42 CFR §423.504(b)(4)(vi)(A)</i>				
	<u>Description</u>	Yes	No	Documentation	Responsible Party or Department

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66.	Do you ensure that either your Standards of Conduct and Ps & Ps or comparable Standards of Conduct and Ps & Ps are distributed to FDR's employees within 90 days of hire / contracting and annually thereafter?				
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FDR Oversight

Element III: Effective Training and Education

42 CFR §422.503(b)(4)(vi)(C) and 42 CFR §423.504(b)(4)(vi)(C)

	Description	Yes	No	Documentation	Responsible Party or Department
67.	Do you ensure that general compliance information is communicated to your FDRs?				
68.	Do you ensure that your non-deemed FDRs' employees receive FWA training within 90 days of hiring/contracting and annually thereafter?				
69.	Do you provide training directly to your FDRs, provide them with FWA training materials or use CMS Learning Network module for FWA training for your FDRs?				

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FDR Oversight

Element III: Effective Training and Education

42 CFR §422.503(b)(4)(vi)(C) and 42 CFR §423.504(b)(4)(vi)(C)

	Description	Yes	No	Documentation	Responsible Party or Department
70.	Do you require your FDRs to maintain records of the FWA training of their employees for ten years, as required?				

FDR Oversight

Element VI: Monitoring and Auditing of FDRs

42 CFR §422.503(b)(4)(vi)(F) and 42 CFR §423.504(b)(4)(vi)(F)

	Description	Yes	No	Documentation	Responsible Party or Department
71.	Do you have a strategy to monitor and audit your first tier entities?				
72.	Does your strategy for monitoring and auditing your first tier entities include:				
A.	Ensuring that they are in compliance with Medicare Parts C and D requirements?				
B.	Ensuring that they are monitoring their downstream entities?				

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Element VI: Monitoring and Auditing of FDRs

42 CFR §422.503(b)(4)(vi)(F) and 42 CFR §423.504(b)(4)(vi)(F)

	Description	Yes	No	Documentation	Responsible Party or Department
73.	Do you monitor and audit your related entities?				
74.	Does your monitoring and auditing work plan include the number of first tier entities that will be audited and how the entities will be identified for auditing?				
75.	If you do not monitor and audit all of your first tier entities, do you perform a risk assessment to identify the high risk first tier entities and then select a reasonable number to audit from the highest risk groups?				
76.	Do you have procedures to ensure that your FDRs are not excluded from participation in Federal health care programs? (42 CFR § 1001.1901)				

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FDR Oversight

Element VI: Monitoring and Auditing of FDRs

42 CFR §422.503(b)(4)(vi)(F) and 42 CFR §423.504(b)(4)(vi)(F)

	Description	Yes	No	Documentation	Responsible Party or Department
77.	Does your system include review of the OIG and GSA exclusion lists prior to hiring or contracting and monthly thereafter for FDRs and their employees either by you, your first entities, or the downstream entities themselves?				

FDR Oversight

Element VII: FDRs: Procedures and System for Prompt Response to Compliance Issues

42 CFR §422.503(b)(4)(vi)(G) and 42 CFR §423.504(b)(4)(vi)(G)

	Description	Yes	No	Documentation	Responsible Party or Department
78.	Do you ensure that needed corrective actions are taken by first tier entities?				
79.	Do you continue to monitor FDR corrective actions after their implementation to ensure that they are effective?				

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Element VI: Monitoring and Auditing of FDRs

42 CFR §422.503(b)(4)(vi)(F) and 42 CFR §423.504(b)(4)(vi)(F)

	Description	Yes	No	Documentation	Responsible Party or Department
A.	Do you ensure that noncompliance or FWA committed by FDRs is well-documented and includes ramifications should the FDR fail to satisfactorily implement the corrective action?				
80.	Do you maintain thorough documentation of all deficiencies identified and the corrective actions taken?				

Compliance Program Effectiveness Self-Assessment Questionnaire Submitted By:

[Name]

[Title]

[Company]

[Address]

[Phone Number]

[Email Address]

(Signature)

(Date)