ATTACHMENT I-A
MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS SELF-ASSESSMENT QUESTIONNAIRE (SA-Q)

(Rev. 6, 10-2016)

Name of Sponsoring Organization:

MA-PD/PDP Contract Numbers:

Name/Title of Person(s) Completing Assessment:

Date of Assessment:

This version of the SA-Q tool is to be used with the Compliance Program Effectiveness Audit Protocol.
Sponsoring Organizations should not interpret every question as a mandatory CMS requirement, but rather as a guide to establish and maintain the core requirements of a compliance program to prevent, detect and correct Medicare program non-compliance and fraud, waste and abuse. This questionnaire is identical to the Medicare Part C and D Compliance Program Guidelines and can be used as a monitoring tool to assist sponsors with evaluating their compliance program for CMS requirements. While Element V of the Medicare Part C and D Compliance Program Guidelines – *Well Publicized Disciplinary Standards* –is a required and critical component of a compliance program, it has been omitted from this version of the SA-Q. However, sponsoring organizations must ensure structures and procedures are in place to successfully implement all required elements of a compliance program Please note the use of this tool by itself does not constitute a formal audit of the compliance program. For example, the formal audit of the compliance program effectiveness should be meet the definition of "audit" noted in the Compliance Program Guidelines and performed by staff not affiliated in any way with the Compliance department.

Directions for completing the self-assessment questionnaire:
Please respond to each question according to the status of your compliance program during the audit review period.
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. For the limited situations when a question does not apply to your organization, enter "N/A" in the "YES/NO" box and document the rationale for the response in the "Documentation" column. If multiple individuals are responsible for the compliance program (e.g. Corporate Compliance Officer, Medicare Compliance Officer, SVP of Audit and Compliance) 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.
- Unless specific reference is made in the question to the term "governing body", it means either the full board or a committee of the board of directors delegated to conduct oversight of the day-to-day operation of the Medicare compliance

program on behalf of the full governing body.

- "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.

	Written Policies and Procedures and Standards of Conduct *42 CFR §422.503(b)(4)(vi)(A); 42 CFR §423.504(b)(4)(vi)(A)*			
No.	**Description**	**Yes/No**	**Documentation (include specific page number, paragraph, section, system, location and/or brief explanation**	**Responsible Party or Department**
1.	Do you have written policies and procedures (Ps & Ps) and/or Standards of Conduct that: (A through G)			
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?			

D.	Provide guidance to employees and others on dealing with potential compliance issues?			
E.	Identify how to communicate compliance issues to appropriate compliance personnel?			

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No.	Description	Yes/No	Documentation (include specific page number, paragraph, section, system, location and/or brief explanation	Responsible Part or Department
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?			
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?			

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	Compliance Officer, Compliance Committee, Governing Body 42 CFR §422.503(b)(4)(vi)(B) and 42 CFR §423.504(b)(4)(vi)(B)			
No.	**Description**	**Yes/No**	**Documentation (include specific page number, paragraph, section, system, location and/or brief explanation**	**Responsible Part or Department**
5.	Does your CEO receive your compliance officer's reports on the status and activities of the compliance program?			
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 governing body in the compliance officer's sole discretion?			

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No.	Description	Yes/No	Documentation (include specific page number, paragraph, section, system, location and/or brief explanation	Responsible Part or Department
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?			
10.	Does your governing body 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 governing body, 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?			

No.	Description	Yes/No	Documentation (include specific page number, paragraph, section, system, location and/or brief explanation	Responsible Part or Department
14.	Do you have a compliance committee whose responsibilities include oversight of the compliance program?			
15.	Does your compliance officer and compliance committee provide the governing body 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?			

	Effective Training and Education 42 CFR §422.503(b)(4)(vi)(C) and 42 CFR §423.504(b)(4)(vi)(C)			
No.	**Description**	**Yes/No**	**Documentation (include specific page number, paragraph, section, system, location and/or brief explanation**	**Responsible Part 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 governing body?			

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No.	Description	Yes/No	Documentation (include specific page number, paragraph, section, system, location and/or brief explanation	Responsible Part 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 training 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?			

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	Effective Lines of Communication 42 CFR §422.503(b)(4)(vi)(D) and 42 CFR §423.504(b)(4)(vi)(D)			
No.	**Description**	**Yes/No**	**Documentation (include specific page number, paragraph, section, system, location and/or brief explanation**	**Responsible Part 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, HPMS memos, 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 governing body 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 governing body, FDRs and their employees and enrollees?			
25.	Does your system allow anonymous reporting and maintain confidentiality to the extent possible?			

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No.	Description	Yes/No	Documentation (include specific page number, paragraph, section, system, location and/or brief explanation	Responsible Part 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 governing body 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?			

	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)			
No.	**Description**	**Yes/No**	**Documentation (include specific page number, paragraph, section, system, location and/or brief explanation**	**Responsible Part or Department**
31.	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?			
32.	Are adequate resources devoted to your audit function considering the scope of your Medicare Parts C and D programs, compliance history, current compliance risks and resources available?			
33.	Do you have a monitoring and auditing work plan that addresses risks associated with Medicare Parts C and D?			
34.	Does your compliance officer receive regular reports from the individuals or component conducting auditing monitoring activities, including providing the status and effectiveness of corrective actions taken?			

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No.	Description	Yes/No	Documentation (include specific page number, paragraph, section, system, location and/or brief explanation	Responsible Part or Department
35.	Does your compliance officer or his/her designees provide updates on the results of monitoring and auditing activities to your compliance committee, CEO, senior leadership and governing body?			
36.	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?			
37.	Does your monitoring and auditing strategies prioritize (a) risks identified through CMS audits and oversight and through your own monitoring; and (b) those risks that have the greatest impact?			
38.	Do you periodically re-evaluate the accuracy of your baseline risk assessment?			
39.	Do you have an auditing and monitoring work plan that includes: (A through C)			
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?			

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No.	Description	Yes/No	Documentation (include specific page number, paragraph, section, system, location and/or brief explanation	Responsible Part or Department
C.	A schedule (with estimated target dates)that lists all auditing and monitoring activities for the calendar year?			
40.	Do you use appropriate methods to: (A through F)			
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?			
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?			
41.	Do you have internal staff dedicated to the audit function? Are procedures in place to ensure auditors are independent of Medicare operations under review to prevent self-policing?			

No.	Description	Yes/No	Documentation (include specific page number, paragraph, section, system, location and/or brief explanation	Responsible Part or Department
42.	Are your auditors knowledgeable about CMS operational requirements for areas under review?			
43.	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?			
44.	Do you conduct a formal audit to evaluate the effectiveness of your compliance program at least annually (once a year)? NOTE: The formal audit should produce an audit report with results and identified root cause(s) and a corrective action plan should be a part of the evaluation. The CMS program audit of a sponsor's compliance program effectiveness does NOT satisfy this audit requirement. Sponsor must conduct its own audit of the effectiveness of its compliance program at least annually.			
45.	Is the annual compliance program effectiveness audit conducted by persons other than your compliance officer and /or compliance department staff?			

No.	Description	Yes/No	Documentation (include specific page number, paragraph, section, system, location and/or brief explanation	Responsible Part or Department
46.	Do you share the results of the audits of the effectiveness of the compliance program with your governing body?			
47.	Do you review the OIG and GSA exclusion lists for your employees (including temporary employees), volunteers, consultants and the members of your governing body prior to hiring/contracting/appointment and monthly thereafter?			
48.	Do you utilize systems and data analysis for monitoring FWA?			
49.	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?			
50.	If you have an SIU, is it accessible through multiple channels, e.g. phone, mail, Internet message?			
51.	Do your SIU and compliance departments communicate and coordinate closely?			

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	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)			
No.	**Description**	**Yes/No**	**Documentation (include specific page number, paragraph, section, system, location and/or brief explanation**	**Responsible Part or Department**
52.	Do you make a reasonable inquiry into all compliance incidents/issues and potential FWA?			
53.	Do you require and ensure that your inquiries are well-documented?			
54.	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?			
55.	Do you undertake appropriate corrective actions that: (A through C)			
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?			

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56.	Do you continue to monitor corrective actions after their implementation to ensure that they are effective?			
57.	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?			
58.	Do you maintain thorough documentation of all compliance deficiencies identified and the corrective actions taken?			
59.	Do you have procedures to refer potential FWA issues to the NBI MEDIC and serious issues of program noncompliance to CMS?			
60.	Do you conclude your investigations of FWA within a reasonable time after the activity is discovered?			
61.	Do you review past paid claims from entities identified in fraud alerts and remove them from their event data submissions e.g. PDEs?			

	FDR Oversight Sponsor Accountability for and Oversight of FDRs 42 CFR §422.503(b)(4)(vi) and 42 CFR §423.504(b)(4)(vi)			
No.	**Description**	**Yes/No**	**Documentation (include specific page number, paragraph, section, system, location and/or brief explanation**	**Responsible Part or Department**
62.	Do you have a process or criteria for determining which delegated entities (and their employees) are properly identified as FDRs subject to Medicare compliance requirements?			
63.	Do you identify and communicate to your FDRs which FDR employees are subject to Medicare compliance requirements?			

	FDR Oversight 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)			
No.	**Description**	**Yes/No**	**Documentation (include specific page number, paragraph, section, system, location and/or brief explanation**	**Responsible Part or Department**
64.	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?			

	FDR Oversight Effective Training and Education 42 CFR §422.503(b)(4)(vi)(C) and 42 CFR §423.504(b)(4)(vi)(C)			
No.	**Description**	**Yes/No**	**Documentation (include specific page number, paragraph, section, system, location and/or brief explanation**	**Responsible Part or Department**
65.	Do you ensure that general compliance and FWA training is completed by your FDRs?			

No.	Description	Yes/No	Documentation (include specific page number, paragraph, section, system, location and/or brief explanation	Responsible Part or Department
66.	Do you ensure that your non-deemed FDRs' employees receive FWA training within 90 days of hiring/contracting and annually thereafter?			
67.	Do you require your FDRs to maintain records of their compliance and FWA training activities for their employees for ten years, as required?			

	FDR Oversight Monitoring and Auditing FDRs 42 CFR §422.503(b)(4)(vi)(F) and 42 CFR §423.504(b)(4)(vi)(F)			
No.	**Description**	**Yes/No**	**Documentation (include specific page number, paragraph, section, system, location and/or brief explanation**	**Responsible Part or Department**
68.	Do you have a strategy to monitor and audit your first-tier entities?			
69.	Does your strategy for monitoring and auditing first-tier entities include: (A & B)			
A.	Ensuring that they are in compliance with Medicare Parts C and D program requirements?			

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B.	Ensuring that they are monitoring their downstream entities?			
70.	Do you monitor and audit your related entities?			
71.	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?			
72.	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?			
73.	Do you have procedures to ensure that your FDRs are not excluded from participation in Federal health care programs? (42 CFR § 1001.1901)			
74.	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?			

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	FDR Oversight 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)			
No.	**Description**	**Yes/No**	**Documentation (include specific page number, paragraph, section, system, location and/or brief explanation**	**Responsible Part or Department**
75.	Do you ensure that corrective actions are taken by first tier entities?			
76.	Do you continue to monitor FDR corrective actions after their implementation to ensure that they are effective?			
77.	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?			
78.	Do you maintain thorough documentation of all deficiencies identified and the corrective actions taken?			