**Medicare Advantage Organization First Tier, Downstream, Related Entities (FDR) Vendor Questions to Consider**

1. Does your organization have a program based on the United States Department of Health and Human Services Office of Inspector General’s published guidance on an effective Compliance Program?
2. Has your organization appointed a representative to serve as the Compliance Officer or in a similar capacity to implement, monitor, educate employees and vendors, and enforce the organizations Compliance Program?
3. Has your organization or its appointed representative reviewed Medicare Advantage Plan Compliance Program Guidance Chapters 21 and 9 as applicable and aware of your organizations responsibilities as a FDR as set forth by the Centers for Medicare and Medicaid Services (CMS)?
4. Have you adopted a Code of Conduct and applicable Policies and Procedures which meet CMS requirements relevant to providing services/ items to patients which may include Medicare, Medicare Advantage Plans, or other government beneficiaries?
   1. Does your organization keep a log certifying that employees have read and agree to comply with the Code of Conduct and Policies and Procedures upon hire and annually thereafter?
      1. Does the log at a minimum include the employees, vendor/contractor, board members, or volunteers name, course completed and training completion date?
      2. Is this log readily available upon request from CMS?
   2. Does your Code of Conduct or applicable Policies and Procedures include language about non-retaliation for good faith reporting of suspected violations, noncompliance or fraud, waste and abuse?
   3. Has your organization adopted a Conflict of Interest Policy or Procedure requiring the disclosure/ reporting of all potential and actual conflicts by employees and potential/ current business partners prior to employment/ contracting and annually afterwards?
      1. Do you monitor to ensure employees and vendors are free of Conflicts of Interest or any reported potential conflicts have been vetted, managed or eliminated if necessary?
   4. Does your organization have a policy prohibiting employment or contracting with an individual or entity sanctioned or excluded from participating in any federally funded health care program?
      1. Does the policy require the immediate removal of an employee from work related directly or indirectly to any state within the U.S. or U.S. federally funded health care program and take appropriate corrective actions including immediate disclosure to your organization any employee or contractor/ vendor identified as an excluded persons or entities?
      2. Do you monitor to ensure employees, board members, volunteers and contractors/ vendors are not sanctioned or excluded from participating in any state within the U.S. or U.S. federally funded health care programs prior to hire/ contracting and monthly after employment or entering into a contract with your organization?
      3. Can you provide a report on a monthly basis to provide at a minimum the following information specific to each employee, board member, volunteer, and contractor/ vendor screened:
         1. Full Name of employee, board member, volunteer, or contractor/ vendor;
         2. Date the individual/ entity was checked:
         3. Date of Report/ File screened against (e.g. LEIE or SAM);
         4. Name/ Initials of individual that screened and cleared the employee, board member, volunteer or contractor/ vendor from being sanctioned?
   5. Does your organization have a well-publicized disciplinary action policy and apply this policy appropriately for compliance related incidents to employees, contractors/ vendors and/ or contractual relationship?
      1. Does the policy or procedure specifically state that any violation of these standards will result in appropriate disciplinary action, up to and including termination of employment?
   6. Does your organization have a policy requiring employees, contractors/ vendors, board members and volunteers to report known and/ or suspected compliance violations to a member of management, the compliance officer or appointed compliance representative or to another mechanism implemented to receive reports of noncompliance (e.g. hotline) without the fear of retaliation?
      1. Does your organization have a policy or procedure requiring documentation of reported compliance issue and resolution of the reported issue to include corrective actions taken to address any substantiated reports including notification to your organization, Medicare contractors, and government agencies as appropriate?
      2. Has the organization taken adequate measures to communicate how to report suspected noncompliance or fraud, waste and abuse to the organizations Compliance Officer or appropriate representative (e.g. hotline posters, discussion during departmental meetings, etc…)?
   7. Does your organization have policies and procedures requiring retention of records in accordance with Medicare requirements (e.g. in most cases records must be retained and available to CMS for a period of at least 10 years or longer)
      1. Are these records readily available upon request by CMS?
5. Does your organization perform compliance training for employees and governing body members (e.g. board of directors) within 90 days of hire and annually thereafter?
   1. Does your organization’s training include completion of CMS’ mandatory Compliance and Fraud, Waste, and Abuse Training?
      1. Relevant CMS Training is located at the two URL’s listed below:
         1. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/MedCandDGenCompdownload.pdf
         2. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/CombMedCandDFWAdownload.pdf
   2. Does your organization’s training educate employees, board members, volunteers, and contractor’s/vendors on relevant policies and procedures to include but not limited to:
      1. The organization’s Code of Conduct;
      2. Non-retaliation for reporting suspected compliance issues;
      3. Disciplinary process; and
      4. Reporting mechanisms available to employees for reporting suspected noncompliance or fraud, waste, and abuse?
   3. Does your organization monitor completion of employees, board members, contractors/ vendors and volunteers regarding training requirements and logs certifying that employees have read and agree to abide by the organizations Code of Conduct and Policies and Procedures?
6. Regardless of whether your organization or affiliates are located within the U.S. and it’s protected territories or outside the U.S., does your organization have a system in place to monitor the effectiveness of your Compliance Program and affiliated entities compliance with Medicare, Medicare Advantage Plans, or other U.S. government or state(s) requirements?
   1. Does your organization develop an audit/ monitoring plan to include review of your business practices to ensure compliance with applicable states within the U.S. and U.S. federal regulations?
   2. Does your organization’s compliance program assess regulatory and compliance risks at least annually?
7. Does your organization or any of your subcontractors/ vendors perform functions which are physically located outside of the United States or one of its territories? Note: Several large MCO’s prohibit the use of offshore contractors without their written approval prior to your organization entering into a contract with said vendor.
   1. Provide the following information for any person or entity contracted to provide services/ items for Medicare, Medicare Advantage Plans, or other governmental beneficiary which are physically located outside of the United States or one of its territories:
      1. Vendor Name;
      2. Offshore Subcontractor Country;
      3. Offshore Subcontractor Address;
      4. Proposed or Actual effective date for offshore subcontract;
      5. Will Protected Health Information (PHI) be provided;
         1. To an Offshore contractor;
            1. Describe PHI to be provided to offshore contractor;
            2. Explain why PHI is necessary to provide to offshore contractor;
         2. Describe alternatives considered to avoid providing PHI and why each alternative was rejected;
         3. Does offshore contracting arrangement have policies and procedures in place to ensure PHI and other personal information remains secure;
         4. Does offshore subcontract arrangement prohibit subcontractor’s access to data not associated with the sponsors contracts;
         5. Does offshore subcontracting arrangement have policies and procedures in place that allow for immediate termination of the subcontract upon discovery of a significant security breach;
         6. Does offshore subcontracting arrangement include all required Medicare Part C and D language (e.g. record retention requirements, compliance with all Medicare Part C and D requirements, etc.);
         7. Does the organization conduct an annual audit of the offshore subcontractor;
         8. Will the audit results by the organization be utilized to evaluate the continuation of its relationship with the offshore contractor; and
         9. Does the organization agree to share offshore subcontractor’s audit results with CMS, upon request?
   2. For your arrangements with offshore subcontractors requiring PHI to be provided to the offshore entity does your organization audit against the criteria listed above at 7(a)(v)(2-10)?