ATTACHMENT III
Compliance Program Data and Document Requests
Compliance Program Audit Protocols

GENERAL INSTRUCTIONS:

Time Period for Universe Requests

The applicable time period for the data requests is 1 year from the date of receipt of the Notice of On-Site Audit and Inspection, or **from [Month DD, YYYY] through [Month DD, YYYY].**

Data Requests

Unless otherwise indicated, please provide all information in **Excel** format. Please do **NOT** submit the actual documents unless specifically requested by CMS. After your organization submits this data to CMS, we will request specific samples or documents needed for our review.

Documentation Requests

For each documentation request, please submit **ONLY** that which is specifically requested. Requests for documentation that do not otherwise indicate a specific format for submission may be submitted in either a **Microsoft Word** or **PDF** format. All data and documentation requests identify the related elements of the compliance program requirements. Your organization must provide a table of contents of the requested documentation by element.

Data and Documentation Requests:

1. *(Applicable to Element I)* All Standards of Conduct/Code of Conduct that were distributed to employees during the audit period. Please state the effective date(s) of these Standards of Conduct.

2. If you have a Medicare Compliance and/or Fraud, Waste, and Abuse ("FWA") Plan, or similar document(s), please provide version(s) in effect during the audit period and state the effective date(s).

3. *(Applicable to Elements I, III, VI)* A current[1] listing of all of your organization's employees[2] (permanent, temporary, full-time, part-time, including senior management), volunteers (e.g. unpaid interns) who have job duties (full-time or part-time) related to your Medicare Advantage (Part C) and or Prescription Drug (Part D) business. This list should include members of your Board of Directors who worked/served at any time during the audit period.

[1] Throughout this request, "current" is defined as at any time during the audit period listed above.
[2] Please note, this request calls for all such employees, volunteers and directors who have worked/served at any time during the audit period, not just those who are working/serving at the time of this data request.

- Please include the following fields: name, title, organizational component, date of hire for all employees hired within the 1 year audit period, physical location and direct phone number.
- Also, please specifically identify in the listing:
  (a) Temporary employees;

  (b) Volunteers; and

  (c) Members of the Board of Directors and date of appointment. Please include all members of the Sponsor's governing body *(e.g., Board of Directors or Board of Trustees)* responsible for Medicare compliance program oversight, along with a short biography of each and any board committee memberships *(e.g., Board Audit Committee or Board compliance committee)*. This material will be utilized by CMS for due diligence and background information purposes.

4. *(Applicable to Element I, IV)* A list of your current Medicare compliance program policies and procedures, including the date of the last revision for each (or last review date, if no revisions were made). Do **NOT**provide copies of your actual policies and procedures. Also, please specifically identify in the listing:

   (a) Policies and procedures revised during the audit period based upon identified non-compliance or FWA issues.
   (b) Policies and procedures updated to incorporate changes in applicable laws, regulations, and/or other Medicare program requirements during the audit period.

5. *(Applicable to Element II)* Please provide the following information regarding your <u>compliance program and staff that support your Medicare compliance function:</u>

   (a) Identify your Compliance Officer/compliance staff and provide current job descriptions and how long they have worked in the position;

   (b) Current resume for Compliance Officer

   (c) A list of all persons who currently serve on your Compliance Committee, along with;
   (1) Job titles/department

   (2) Length of time with the organization

   (3) Brief description of each person's responsibilities (if any) on the Compliance Committee (*e.g. member of a sub-committee*);

(d) Your Compliance Committee Charter and its effective date

6. *(Applicable to Element II)* Identify each compliance committee meeting (*other than Board-level Compliance Committees, which are covered in Request No. 7 below)* during the audit period at which Medicare Part C and/or Part D compliance and/or Medicare FWA issues were a topic on the agenda and/or were discussed. Also, provide the following:

   (a) Agendas and meeting minutes[3] *(you may redact any non-Medicare issues)*

   (b) All documentation that details the content of the meeting, including specific reports, charts, or other documents that the committee meeting minutes refer to or that were otherwise reviewed or discussed during each meeting. In other words, provide data that details the dates of the meetings, what was discussed, materials that were shared at the meeting regarding compliance (e.g. *PowerPoint presentations, emails, handouts, reports, memoranda, etc.)*

   (c) Action items assigned to correct compliance issues and reports provided to the senior-most leader and/or governing body on the status of the compliance program.

7. (Applicable to Element II) Identify each Board meeting and *Board-level Compliance Committee* meeting during the audit period at which Medicare Part C and/or Part D compliance and/or Medicare FWA issues were a topic on the agenda and/or were discussed. Also, provide the following:

   (a) Agendas and Meeting minutes[4] *(you may redact any non-Medicare issues)*

   (b) All documentation that details the content of the meeting, including specific reports, charts, or other documents that the Board meeting minutes refer to or that were otherwise reviewed or discussed during each meeting. In other words, provide data that details the dates of the meetings, what was discussed, materials that were shared at the meeting regarding compliance (e.g. *PowerPoint presentations, emails, handouts, reports, memoranda, etc.)*

[3] The Compliance Program Guidelines provide Sponsors the flexibility to reflect the substance of meetings in either formal minutes or in whatever documentation they choose. Where "minutes" are requested and your organization's minutes do not reflect the substance of the meeting, you may submit whatever minutes exist *plus* any other documentation reasonably contemporaneous with the meeting that reflects the substance of the meeting (e.g., a memorandum, an email, etc.) in order to establish reasonable oversight.

[4] See footnote 3.

(c) With respect to Medicare compliance and FWA issues presented to the Board, please provide documentation of the actions or decisions made to ensure the issues are resolved.

(d) In addition to the meeting content, if there are other oversight activities outside of Board meetings, please provide documentation.

8. *(Applicable to Element III and Oversight of FDRs)* Provide a list of all general Medicare compliance education provided to your employees volunteers, members of the governing body, first-tier, downstream and related entities (FDRs) and/or others during the audit period.

(a) Please include the date, topic, audience, and method of education.

9. *(Applicable to Element III and Oversight of FDRs)* Provide a list of all Medicare FWA training provided to your employees volunteers, members of the governing body, FDRs and/or others during the audit period.

(a) Please include the date, topic, audience, and method of education.

10. *(Applicable to Oversight of FDRs*) Provide a brief statement explaining the mechanism used to provide FWA training to FDRs:

(a) Sponsor provided FWA training to FDRs, and/or

(b) Sponsor provided FWA training materials to FDRs, and/or

(c) FWA training provided to FDRs by some other means (please specify)

11. *(Applicable to Element III)* Provide a description, including examples, of how it was determined that training and education were effective in reducing compliance and FWA risks.

12. *(Applicable to Element IV and Oversight of FDRs)* Provide evidence that you have provided reporting mechanisms for employees, FDRs, and enrollees (e.g. hotline number).

13. *(Applicable to Element IV)* Provide a brief description of the mechanism used to communicate information and regulatory changes from the compliance officer to others (e.g. employees, FDRs).

14. (Applicable to Element IV) Provide a list of all HPMS Memos received during the audit period indicating the following:

(a) HPMS memo date

(b) Date compliance department disseminated to Medicare C/D business owner

(c) Identify Medicare C/D business area/owner responsible for implementing policy changes/updates in HPMS memo

15. *(Applicable to Elements II, IV, VII and Oversight of FDRs)* Provide a list of all reports of program non-compliance received from any source during the audit period including, but not limited to all hotline calls received. Please provide the following information regarding each report:

(a) Case number or reference ID number;

(b) Source of the report (e.g. employee, FDR, enrollee);

(c) How issue as reported (e.g. hotline, in-person, manager, website);

(d) Date issue was reported;

(e) Description of issue;

(f) Date of resolution (if not received, please note); and

(g) How issue was resolved.

16. *(Applicable to Elements II, VII)* provide a current list of all potential incidents or investigations of FWA identified by any source (e.g. auditing, monitoring, self-evaluation, member complaints, grievances, etc.) during the audit period Please include the following information:

(a) Date incident detected;

(b) Method and/or source by which incident detected;

(c) Nature of the incident detected;

(d) Operation area affected;

(e) Case number or reference ID number;

(f) Date of resolution;

(g) Explanation of how the issue was resolved.

(h) Geographic area where incident occurred (by county), particularly noting whether the investigation occurred in any of the following counties: Harris (TX), Kings (NY), Los Angeles (CA), Miami Dade (FL); Baton Rouge Parish (LA); Wayne (MI);Houston (TX); Dallas (TX); Pinellas (FL); Cook (IL).

17. *(Applicable to Element V)* Identify the location of your disciplinary policies and procedures - Do not provide copies of the text of the disciplinary policies.

(a) Title and where located (e.g located in Standards of Conduct at page(s) ___, Policy No. ___ titled _____, etc.)

18. *(Applicable to Element V)* Provide a few examples of the mechanisms used to publicize disciplinary standards for employees and FDRs.

19. *(Applicable to Element V)* Provide a list of all employees who have been identified as having engaged in unethical, non-compliant or illegal conduct or who otherwise violated standards of conduct for noncompliance with Medicare requirements and/or participated in incidents of FWA, including the following:

(a) Case number or reference ID number;

(b) Title and operational area of employee;

(c) Source of the report (e.g. employee, FDR, enrollee)

(d) How issue was reported (e.g. hotline, in-person)

(e) Date violation was reported;

(f) Description of violation;

(g) Date of disciplinary action; and

(h) Description of the disciplinary action taken (if none taken, please note).

20. *(Applicable to Element V)* Describe how the Sponsor determines that disciplinary policies and disciplinary actions are applied consistently.

21. *(Applicable to Element VI)* Provide all formal risk assessments by which you identified compliance and potential FWA risks with respect to Medicare Part C and/or Part D programs during the audit period.

22. *(Applicable to Element VI)* Provide all audit and monitoring work plans in effect at any time during the audit period applicable to the Medicare Part C and/or Part D programs.

23. *(Applicable to Element VI and FDR Oversight)* Provide a current list of all systems and/or mechanisms used to conduct internal monitoring, auditing, and tracking Medicare compliance and potential FWA issues in the following areas:

    (a) Medicare Part C and/or operational areas; and

    (b) FDR/delegation oversight.

24. *(Applicable to Element VI*) Provide a list of all monitoring activities conducted during the audit period in the following areas: formulary administration, Part C and D claims payment, Part C organization determinations, appeals and grievances, Part D coverage determination, appeals, and grievances, agents/brokers, enrollment/disenrollment, LEPs, compliance program, credentialing/re-credentialing and human resources (e.g., hiring). Please provide the number of deficiencies found, if any, as a result of these monitoring activities.

25. *(Applicable to Element VI)* Provide a list of all auditing activities conducted during the audit period in the following areas: formulary administration, Part C and D claims payment, Part C organization determinations, appeals and grievances, Part D coverage determination, appeals, and grievances, agents/brokers, enrollment/disenrollment, LEPs, compliance program credentialing/re-credentialing and human resources (e.g., hiring) and, as to each, state whether one or more deficiencies were found. Please provide the date these auditing activities were conducted and the number of deficiencies found, if any. Also, indicate which activities were conducted by external auditors.

26. *(Applicable to Element VI)* Provide a description, including examples, of how it was determined that internal auditing and monitoring activities were effective in reducing compliance and FWA risks.

27. *(Applicable to FDR Oversight)* Provide a current list of the names and functional responsibilities of all of your first-tier entities. Please identify if each first-tier entity is a "deemed" or "non-deemed" provider/organization.[5]

28. *(Applicable to FDR Oversight)* Please provide documentation that identifies your process or procedures ensuring that first tier and related entities are auditing and monitoring their

[5] To qualify for "deemed" status, providers/ organizations must meet certification requirements through enrollment in Medicare Parts A or B or accreditation as supplier of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). These organizations are deemed compliant to have met the training and educational requirements for fraud, waste and abuse. If an organization qualifies for deemed status, please retain records or evidence of certification. Sponsors may be asked to produce documentation for audit purposes. See Chapter 50.3 of Chapter 9 of the Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual.

downstream entities for compliance with CMS requirements (e.g. screening against OIG/GSA exclusions lists, providing general compliance and FWA training as required, requirement that FDR employees report potential FWA, etc.)

.29. *(Applicable to FDR Oversight)* Please identify all first tier entities that you audited during the audit period, together with the dates on which the auditing occurred. Indicate the deemed or non-deemed status.

(a) If you did not audit all of your first tier entities during the audit period, please describe how your organization selected those that were audited.

30. *(Applicable to Element VI)* Please list the name, job title and department of all persons who conducted internal auditing of your Medicare Parts C and/or D operational areas during the audit period and specify the operational area that each person audited.

31. *(Applicable to Element VI)* Did you conduct an audit of the effectiveness of the Medicare compliance program during the audit period? (Yes or No) If yes, please provide the following:

(a) State who conducted the audit,

(b) Date audit conducted

(c) Provide the audit report or analysis, and the date when it was conducted and please provide the audit report.

32. *(Applicable to Elements VI and VII)* Provide a description, including examples, of specific monitoring activities performed during the audit period to prevent and detect FWA (e.g. data analysis) and response to CMS Fraud Alerts.