# Medicare

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<th>POLICY #:</th>
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<td>Medicare Compliance</td>
<td>COMP 201</td>
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<td>01/21/2013</td>
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<th>POLICY TITLE:</th>
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<tr>
<td>Creation and Maintenance of Medicare Compliance Policies, Procedures and other Compliance Documents</td>
<td>03/09/2017</td>
<td>Nancy Mundy</td>
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<tr>
<td>Christina F. Melton</td>
<td>Part C and Part D program (e.g., MA, PDP, MMP, etc.)</td>
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## PURPOSE

The purpose of this document is to implement the relevant provisions of 42 C.F.R. §§ 422.503(b)(4)(vi), and 423.504(b)(4)(vi), Chapter 9 of the PDBM, and Chapter 21 of the MMCM, which requires Part C and Part D sponsors to develop and implement an effective compliance program, including the maintenance of written policies and procedures and standards of conduct.

## POLICY

To articulate Aetna’s compliance and ethical standards and practices, and its commitment to comply with all applicable federal and state laws and regulations, Aetna has established written policies and procedures, including a Medicare Compliance Plan to implement the Medicare Compliance Program. These policies and procedures, in concert with the COC, direct employees, Directors, and FDR employees in implementing the elements of the Medicare Compliance Plan.

Aetna’s Medicare Compliance Policies and Procedures are reviewed and updated at least annually, and when there are significant changes to applicable federal and state laws, regulations, or program requirements. The processes defined within this policy may be modified by Aetna based upon the unique circumstances of specific plan contracts (e.g., MMP demonstration plans, etc.). The definitions/acronyms used within this policy are listed below.

## DEFINITIONS/ACRONYMS

- **BCI** – Business, Conduct & Integrity
- **BOD** – Board of Directors
- **CMS** - Centers for Medicare & Medicaid Services
- **COC** – Code of Conduct
- **FDR** - First Tier, Downstream, and Related entities
- **FWA** – Fraud, Waste, and Abuse
- **MA** – Medicare Advantage
- **MCC** – Medicare Compliance Committee
- **MCO** - Medicare Compliance Officer
- **MMCM** - Medicare Managed Care Manual
- **MMP** – Medicare-Medicaid Plan
- **OIG** – U.S. Department of Health & Human Services’ Office of Inspector General

Aetna Health and/or Aetna Life Insurance Company
For Internal Use Only

COMP-201 Creation and Maintenance of Medicare Policies and Procedures Procedure
**PROCEDURE**

1. **Creation of Medicare Compliance Policies and Procedures**
   
   When the need arises, requiring Medicare Compliance to develop and implement a policy and procedure to address new or revised law, regulations, or program requirements, either an existing policy will be revised or a new policy will be drafted. When a new policy is drafted:

   A. A New Medicare Compliance Policy will be drafted utilizing the Medicare Compliance Policy and Procedure Template. Desktop guides containing procedural details may be in place to further describe the policy activities.

   B. Requirements and responsibilities will be outlined in the draft policy.

   C. Once a draft policy is created, it will be reviewed and approved by the Medicare Compliance staff responsible for the affected area.

   D. The draft policy will then be routed to other Medicare Compliance staff and/or business partners for review, as needed, to ensure that there are no conflicts to other business or compliance policies and procedures.

   E. The draft policy will next be reviewed by the MCO or his or her designee for comments and feedback. Medicare Legal Counsel may be consulted for additional review and input.

   F. The MCO will conduct a final review of the draft policy and make any revisions, before issuing his/her approval. Once approved by the MCO, the policy can be implemented as a final policy and will be loaded to the Medicare Compliance policy repositories.

2. **Maintenance and Review of Existing Policies and Procedures**

   Existing Medicare Compliance Policies and Procedures and the Medicare Compliance Plan are reviewed at least annually and revised if needed, or when there are legal, regulatory, or program changes that require Policy and Procedure revisions. When existing policies are updated:

   A. Updates are noted via track changes in the document.

   B. The revised document is submitted to the appropriate member or members of the Medicare Compliance Department for review and comment. Medicare Legal Counsel may be consulted for additional review and input.
C. The MCO will conduct a final review of the draft policy and make any revisions before issuing his/her final approval. Once approved by the MCO, the policy can be implemented as a final policy and will be loaded to the Medicare Compliance policy repositories.

3. **Storage and Communication of Policies and Procedures**

A. Medicare Compliance Policies and Procedures, including the Medicare Compliance Plan, are maintained on Aetna’s intranet, the AetNet, which is accessible on an ongoing basis to all Medicare supporting employees.

B. Medicare Compliance Policies and Procedures are communicated to employees who support Aetna’s Medicare business within 90 days of hire and annually thereafter through Aetna’s BCI training. In addition to these policy communications, Aetna’s other foundational documents as defined below are also communicated at these same timeframes.

C. Policy changes are circulated through various mechanisms: staff meetings; MCC presentations; intranet postings, etc.

4. **Record Retention**

When a new policy is created that replaces an existing policy, the obsolete policy is archived in accordance with Aetna’s Records Retention Schedule and CMS requirements.

5. **Other Foundational Compliance Policy Documents**

A. **Aetna Code of Conduct:**
Medicare Compliance participates, as needed, in the company’s ad hoc or periodic review and update of the COC. This document provides the overarching principles under which Aetna operates, describes compliance expectations (e.g., obligation to report potential/actual non-compliance, FWA, or violations to COC or company policies, etc.) and the company’s commitment to comply with all applicable federal and state standards. The COC is approved by Aetna’s BOD when material changes are made to the content.

B. **Aetna Medicare Compliance Plan:**
Aetna constructed a Medicare Compliance Program to meet the obligations specified in regulatory and sub-regulatory guidance from CMS which were based upon the United States Federal Sentencing Guidelines seven elements for compliance plans. These elements are specifically defined within the CMS Compliance Program Guidelines found in Chapter 9 of the PDBM and Chapter 21 of the MMCM. Aetna’s program is designed to prevent, detect and correct Aetna’s Part C and D Medicare noncompliance and FWA. Aetna has established various policies, processes, and procedural guides which
collectively compose the program. The Aetna Medicare Compliance Plan is a document developed and maintained by Medicare Compliance that provides an overview of Aetna’s Medicare Compliance Program and is an evergreen document. It is reviewed at least on an annual basis and updates are made if needed.

SOURCES/REFERENCES:

Regulatory References:
42 CFR § 422.503(b)(4)(vi)(A)
42 CFR § 423.504(b)(4)(vi)(A)
Prescription Drug Benefit Manual, Chapter 9
Medicare Managed Care Manual, Chapter 21

Related Policies and Procedures/Desk References/Job Aides:
Aetna Record Retention Schedule: http://aetnet.aetna.com/LawNet/Records_Ret_Sched.html
Aetna Code of Conduct
Aetna Medicare Compliance Plan

REVIEW:

Accountable for Policy Maintenance: Nancy Mundy, Sr. Director, Compliance/Meegan Johnson, Director, Compliance
Accountable for Implementation: John Wells, Medicare Compliance Officer(MCO)

Approval Signature & Date:
Legal: Nicole Cerquitella, Medicare Legal Counsel 03/09/2017
Compliance: John Wells, Medicare Compliance Officer 02/21/2017

Review & Revision History:

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<td>1.0</td>
<td>Updated as part of P&amp;P regulatory update project; Supersedes Policy 121</td>
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<td>02/07/2014</td>
<td>2.0</td>
<td>Annual review and update</td>
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Review/Approval Date:

\[\text{Signature} \]

Committee Co-Chairperson

Aetna Pharmacy Management Quality Oversight committee (APMQOC)

\[3/29/2017\]

Approval Date
**PURPOSE**

The purpose of this document is to implement the relevant provisions of 42 C.F.R. §§ 422.503(b)(4)(vi), and 423.504(b)(4)(vi), Chapter 9 of the PDBM, and Chapter 21 of the MMCM, which requires Part C and Part D sponsors to have an effective compliance program, including the implementation and operation of an effective system for routine monitoring and auditing, identifying compliance and FWA risks with prompt responses, as necessary, in order to protect the Medicare program.

**POLICY**

Aetna will comply with all applicable federal and state laws and regulations regarding the establishment of its Medicare Compliance Plan and Work Plan(s). Aetna has established and maintains a process to audit and/or monitor its Medicare functions, including those performed by FDRs, for compliance with Medicare regulatory and sub-regulatory guidance, compliance with contractual terms, compliance with applicable federal and state laws, and adherence to internal policies and procedures in order to identify potential or actual compliance and/or FWA risks. Aetna complies with the prompt response requirements when such risks are ascertained. In addition, Aetna assesses the overall effectiveness of the Medicare Compliance Program on a periodic basis. Desk reference guides or other information may be in place to define further procedural actions of each of the processes described in this policy. The processes defined within this policy may be modified by Aetna based upon the unique circumstances of specific plan contracts (e.g., MMP demonstration plans, etc.).

In addition to the Medicare Compliance activities within this policy, the Internal Audit Department or other areas may conduct risk assessments and subsequently develop audit plans. These areas maintain their own policies and procedures associated with these processes. Medicare Compliance collaborates with these areas to leverage internal resources and enhance multi-disciplinary collaboration and visibility. The definitions/acronyms used within this policy are listed below.

**DEFINITIONS/ACRONYMS**

- **BOD** – Board of Directors
- **CA** – Corrective Action(s)
- **CAP** - Corrective Action Plan
**Processes**

1. **System to Identify Compliance Risks**

Medicare Compliance may coordinate with Aetna’s Internal Audit Department or other areas while conducting annual baseline risk assessments relating to Medicare compliance and FWA risk areas. Each business area is assessed and consideration may be given to size of the department, complexity of work, past compliance issues, degree of regulatory change, auditing and monitoring results, and areas of interest by regulators or other external parties. These assessments are designed to review, rank risk through normative and empirical modeling, and prioritize the key regulatory risks for all Medicare business operations into a range of Risk Priority categories. The top Risk Priority scores are used for driving the development of the annual Medicare Compliance Work Plans (“Work Plan”). The MCO is integral to this process, and the results of the risk assessment are reviewed with the MCC.

Inclusive in the Work Plans are the completion of First Tier Risk Assessments. The assessment includes all First Tier entities servicing Aetna Medicare contracts. First Tier entities may be scored as First Tier Types. First Tier entities are scored individually. The highest risk entities are the priority for the development of a list of targeted First Tier entities to be evaluated during the calendar year as part of the Work Plan. Other considerations during the stratified First Tier selection for inclusion in the Work Plan include any recommendations received, past audits, etc.
Since risks change and evolve with changes in the law, regulations, CMS requirements and operational matters, Medicare Compliance’s risk assessments are re-evaluated at least semi-annually to assess the accuracy of the baseline assessment. In addition, off-cycle risks are addressed as they arise.

2. **Annual Medicare Compliance Work Plan**

   A. **Development:**
   Using the results of the risk assessment, the MCO, with participation of the Medicare Compliance staff as needed, will develop an annual Work Plan to define the schedule of the monitoring and auditing activities of the prioritized risk areas. The Work Plan defines the auditing and monitoring activities for the relevant calendar year such as the objective, frequency, and schedule, etc. Auditing and monitoring activities are assigned based on knowledge and expertise of the reviewers, as well as resource availability and timing needs. The Work Plan will define the process for responding to audit and/or monitoring results and conducting follow up reviews of areas found to be non-compliant to determine if the implemented CAs have fully addressed the problems.

   The Work Plan also contains the annual First Tier Risk Assessment which defines the number of First Tier entities strategically selected for review (e.g., “60”, “at least 60”, etc.) and how they were selected (e.g., “based upon completion of a risk assessment”, etc.). The stratified selection of First Tiers from the highest risk entities in the First Tier risk assessment are listed in the Work Plan. Targeted Downstream and/or Related entities may also be added to the Work Plan. Medicare Compliance collaborates with business partners for completion of these audits. A designated Medicare Compliance audit tool is used for these reviews and includes Compliance Program components such as the completion of the initial 90 day FWA training, monthly employee screening against the sanction and debarment lists, First Tier oversight of their Downstream entities, etc.

   Aetna maintains a comprehensive approach to oversee Aetna’s FDRs which also includes “Relationship Managers” who are business partners that are responsible for the FDR and specialized oversight units/practices. The associated business areas of these processes maintain their own policies and procedures (e.g., National Delegation Policy and Procedures 106 and 107, Information Privacy & Security assessment practices, Agent Oversight, etc.). See the supplementary *Aetna FDR Program Description* for additional details.

   B. **Execution of the Work Plan:**
   The Medicare Compliance staff have access to company personnel, documents, legal counsel, operational units, and FDRs as needed to support the Work Plan activities.
The audits in the Work Plan are led or overseen by Aetna Medicare Compliance to ensure compliance with Medicare regulations and other applicable requirements. The audit methodology and scope will include appropriate methods for selecting facilities, pharmacies, providers, claims, and other areas for audit, as applicable; determining appropriate sample sizes; extrapolation of audit findings in compliance with generally accepted auditing standards; application of targeted or stratified sampling methods; and the use of special targeted techniques based on aberrant behavior. Audits will typically be an assessment of compliance with Aetna’s internal process and procedures. Where there is specific operational, clinical and/or compliance-related expertise that is required, the audit lead will solicit the assistance of other operational and clinical staff to assist in the review. When audit team proficiency cannot be achieved internally, the targeted audit will be outsourced to an external review organization for completion. In all cases, the audit lead is independent of the area/function being audited, allowing for an unbiased audit opinion.

The Work Plan is dynamic and may need to be modified as higher risks/priorities arise, however, any changes made to it must be approved by the MCO.

C. Tracking & Reporting Results:
Work Plan progress, including its subset FDR audits and monitoring events, will be tracked by the MCO. The results of all Work Plan activities are regularly reported to the MCO, along with the status and effectiveness of any CAs. Work Plan activities are subject to specific standards. For example, the results of the Work Plan audits shall be reflected in standard audit reports that meet CMS requirements and include key stakeholders during distribution.

The MCO or designee(s) provide updates on Work Plan, including any approved changes, to the MCC, and when appropriate to any of the following: the Aetna Chief Ethics and Compliance Officer, the Aetna Chief Executive Officer for Medicare, Aetna Senior Leadership, and Aetna’s BOD or subset. These reports may be in the form of an oral report, written report and/or dashboard view. See Policy and Procedure COMP203 – Medicare Compliance-Lines of Communication Policy and Procedure for additional details on communication with key constituents.

3. Audit of the Aetna Medicare Compliance Program

Aetna’s Medicare Compliance Program and Medicare Compliance functions and activities will be audited by a third party. Results of the compliance program audits are shared with the MCO, the Chief Ethics and Compliance Officer, the MCC members of senior leadership and the Aetna BOD or Audit Committee of the BOD, as applicable. Any identified deficiencies result in corrective actions for issue resolution.
4. OIG/SAM Exclusion and Debarment Screenings

Various business areas within Aetna (e.g., Human Resources, Credentialing, Broker Services, etc.) conduct OIG SAM sanction and debarment screenings. These areas maintain their own policies and procedures related to these processes. Any potential matches are investigated with appropriate actions taken.

In addition, Aetna’s Medicare contracts with First Tier entities require that they perform the same pre-hire/contracting and monthly verifications against the same lists for all of their employees and Downstream entities that support Aetna’s Medicare business. Attestations or other methods of verification may be implemented within the business to evaluate their compliance. Otherwise, compliance is assessed for the applicable First Tier entities that are selected for the annual Work Plan. In the event that a First Tier entity is unable to evidence compliance with this requirement, CAs will be taken in accordance with contractual provisions.

5. Aetna’s Special Investigation Unit (SIU)

Aetna’s SIU is responsible for the identification of potential FWA, timely initiation of investigations, and, where potential FWA is identified, reporting such to the NBI MEDIC and/or law enforcement as warranted. Medicare Compliance supports reporting of concerns to the SIU. See COMP203 – Medicare Compliance-Lines of Communications Policy and Procedure identifies the various methods available for reporting of FWA concerns to Medicare Compliance and the SIU. In addition, Medicare Compliance personnel and the MCO are accessible to the SIU personnel on an ongoing basis. The SIU interacts frequently with Medicare Compliance and presents routinely to the MCC regarding case file trends, emerging schemes, and case metrics. The SIU maintains an Aetna Health Care Anti-Fraud Plan and associated manual, Special Investigations Unit Policies and Procedures on these practices.

A. Data Analytics:

Aetna’s SIU is responsible for performing certain data analytics as a means to prevent and identify potential FWA. The Aetna SIU utilizes information technology platforms and software products, and proactively data mines for fraudulent or abusive billing patterns regularly. The suite of products utilized within the SIU enable capabilities including but not limited to predictive analytics, top-down analysis, rules based and anomaly detection. The Aetna SIU also receives suspect pharmacy/prescriber leads generated by data mining from Aetna’s PBM. A combination of rules based examinations and predictive analytics is executed on claims on a daily/weekly/monthly basis to generate leads. Both pre-payment and post-payment analytics are executed.

B. NBI MEDIC/Referrals to NBI MEDIC:
Aetna’s SIU coordinates and collaborates with the NBI MEDIC on potential FWA investigations. Specifically, if during the course of an investigation SIU identifies a case involving potential fraud, waste or abuse meeting any of the below criteria, SIU will refer the case to the NBI MEDIC in accordance with the guidance for such submissions.

1) Suspected, detected or reported criminal, civil, or administrative law violations;  
2) Allegations extending beyond Part C and D plans, involving multiple health plans and states, or widespread schemes;  
3) Allegations involving known patterns of fraud;  
4) Patterns of fraud, waste or abuse that threaten the life or well-being of beneficiaries; and  
5) Schemes with large financial risk to the Medicare program or beneficiaries.

Aetna's SIU collaborates on cases with other functional areas (e.g., Investigative Services), as needed. Referrals to NBI MEDIC related to agents are made by Aetna's Agent Oversight unit. The SIU also processes any Requests for Information (RFI) that may be received from the NBI MEDIC and/or other authoritative bodies (e.g., OIG, CMS, law enforcement, etc.).

C. Responding to CMS-Issued Fraud Alerts:  
On occasion, CMS will issue Fraud Alerts via their HPMS notification System. Upon receipt of the Alert, Aetna Medicare Compliance will add the notification to the Alert distribution system (e.g., QuickBase), and distribute to all impacted parties (e.g., SIU) for processing under SIU policies and incorporation into their case tracking systems, as applicable.

D. Providers with History of Complaints:  
SIU maintains case files for a period of ten (10) years in accordance with Aetna's record retention policy and procedure. See Aetna’s Record Retention Policy.

At the launch of each investigation, the SIU reviews case history to determine whether prior complaints were made, and the nature of any prior complaints. Completion of this activity may result in either a case re-opening or new case assignment.

6. Conducting a Timely and Reasonable Inquiry of Detected Offenses

A. Timeliness of Investigation:  
Aetna is committed to initiating investigations into potential compliance issues or suspected FWA in a timely manner. Three main systems receive and investigate these potential issues as described below.

1) Aetna Core Compliance: General compliance and ethics concerns are received through multiple reporting channels such as Aetna's AlertLine® (a toll-free ethics telephone hotline), the AlertLine® intranet website, the Aetna Compliance email box, the Investigative Services email box, and a Post Office Box in West
Hartford, CT. The Ethics Office follows Aetna’s Compliance/Ethics Complaints and Concerns Handling Policy to ensure prompt and complete review and/or investigation of all compliance and ethics matters received by the Ethics Office through the various reporting channels at Aetna. Investigations are typically initiated within 2 business days (See Routine Investigations Manual Section 5.B). A database (e.g., TrakEnterprise) is used to record all compliance and ethics concerns received by the Ethics Office.

2) SIU: Potential FWA investigations are received by the SIU through a variety of available mechanisms and are initiated within 2 weeks. In the event the SIU or MCO determines that Aetna does not have the time or resources to investigate an instance of potential fraud or abuse in a timely manner, the SIU will refer the matter to the NBI MEDIC within 30 days of the date the potential fraud or abuse was identified. In addition, other investigative units (e.g., Investigative Services and Agent Oversight) ensure timely processing of potential FWA cases.

3) Aetna Medicare Compliance: Issues are received by, identified by, or directed to the Aetna Medicare Compliance team through a variety of available mechanisms (See COMP 203 – Medicare Compliance-Lines of Communications Policy and Procedure). Potential issues may originate from a variety of sources (e.g., self-evaluations, auditing, monitoring, regulatory inquiries, CTMs, CMS, employee referrals, etc.). Issues received by Aetna Medicare Compliance require initial investigation to be initiated no later than 2 weeks (14 calendar days) after the date that the potential issue was identified.

B. Documentation:
Case investigations are recorded in the manner and practice prescribed by the policies that are in place for each of the above systems. Compliance inquiries are well-documented through Aetna Medicare Compliance procedures:

1) Upon identification of a potential issue, Medicare Compliance creates a “Potential Issue” in eGRC. The potential issue is assigned a Business Owner.

2) The Business Owner, in partnership with Medicare Compliance, is engaged in investigating the potential issue to confirm or refute whether an issue of noncompliance exists. If noncompliance is confirmed, an assessment of the issue, including root cause analysis, impact of the issue (number of members/financial impact), and duration of the issue is conducted and appropriate CA is taken. If, after investigation, no issue of noncompliance is substantiated, the matter is closed and reported, as necessary, to the person or entity that reported the potential issue.

3) Medicare Compliance staff provides reports to the MCO and the MCC, as required, on potential issue investigations and results.
7. Corrective Actions

CAs to address non-compliance or suspected FWA are developed and implemented on a case-by-case basis. The MCO or his/her designee oversees all CAPs for each issue. CAPs are designed to correct the underlying problem leading to the issue of non-compliance to prevent future instances of or continued non-compliance of the nature identified in the issue, and will include timeframes for specific achievements.

A. CAP implementation:
1) General Compliance and Ethics issues: In accordance with Aetna’s Code of Conduct, and related Workplace Policies, CAs may include (i) employee discipline (e.g., coaching, written warnings, suspension and other actions up to and including employee termination), (ii) new and/or revised policies/procedures/workflows, and (iii) employee training.
2) Potential FWA issues are referred to CMS or to the NBI MEDIC by the MCO, his/her designee, the SIU or another Aetna party, as necessary.
3) CAs may include overpayment recovery, payment suspension, Prescription Drug Event correction/deletion, and other actions up to and including provider termination.
4) Issues of non-compliance require remediation and any CAPs are reviewed by Aetna Medicare Compliance to determine the reasonableness of the plan of action to address compliance deficiencies. In addition, Aetna Medicare Compliance tracks the completion of the CAP to resolution.
5) CAPs to address non-compliance by an FDR are monitored by the appropriate oversight committee, as applicable. Each committee maintains their own supporting policies. Medicare Compliance sponsors a FDR Oversight Committee that oversees FDR CAPs, high risk FDRs, etc. In addition, FDRs may be presented to the MCC. See the Aetna FDR Program Description for additional details.

B. Aetna Medicare Compliance Procedures:
1) CAPs are added to the Medicare Compliance issue tracking database.
2) Status meetings between the MCO and/or a Medicare Compliance designee and the Business Owner(s) may occur to ensure progress on the CAP.
3) CAPs must address the root causes of any deficiency to correct the underlying problem and prevent future reoccurrences. These may include interim and long term solutions.
4) Upon completion of CAP implementation, Medicare Compliance will validate the effectiveness of the CAs such as through testing results, schedule a follow-up review, or develop and implement ongoing monitoring activities.
5) Medicare Compliance maintains and/or has access to documentation of all deficiencies and CAs taken.
6) Routine reporting of the status/progress of CAPs are provided to the MCO and other governing bodies (e.g., MCC, etc.) and when appropriate to any of the following: the Aetna Chief Ethics and Compliance Officer, the Aetna Chief Executive Officer for Medicare, Aetna Senior Leadership, and Aetna’s Board of Directors or subset. These reports may be in the form of an oral report, written report and/or dashboard view.

8. Procedures for Self-Reporting Potential FWA and Significant Non Compliance

In the event that potential FWA is identified (including at the FDR level), Aetna promptly refers the issue to the NBI MEDIC, in accordance with the guidance defined by the NBI MEDIC (see SIU’s Aetna Health Care Anti-Fraud Plan and Special Investigations Unit Policies and Procedures manual).

In the event of an instance of significant non-compliance, Aetna’s MCO or his/her designee will report such incident to CMS as soon as possible after discovery, in accordance with relevant regulatory requirements and guidance.

In certain situations, Aetna engages CMS in order to report proactively key information (e.g., upcoming provider terminations, changes to FDR contracts for key functions, etc.). PBM changes are reported to Aetna’s CMS Account Manager at least 60 calendar days prior to the effective date of the new contract or the date the new PBM would begin providing services to beneficiaries, whichever is earlier. In instances of a contract change occurring within less than 60 days, Aetna must notify within 5 days of signing the new contract. Other FDR changes are evaluated by the MCO for similar proactive reporting using the same timeframe as referenced in this section.

9. Auditing by CMS or its Designee

In accordance with Aetna’s contracts with CMS, Aetna provides access to any regulatory agency or auditor acting on behalf of the federal government to conduct a desk review, an on-site audit or other activities. In addition, Aetna’s contracts with First Tiers include provisions ensuring the external entity adheres to the same requirements. Responses to requests for information or information requested by the NBI MEDIC will be responded to within the timeframe required. In the event that additional time is needed, Aetna will communicate such needs directly with requestor.

SOURCES/REFERENCES:

Regulatory References:
- 42 CFR 422.503, 42 CFR 423.504
DEPARTMENT: Medicare Compliance

POLICY #: COMP 202

Version #: 7.0

POLICY TITLE: Medicare Compliance Risk Assessment, Auditing, Monitoring and Issue Management Policy and Procedure

EFFECTIVE DATE: 01/21/2013

- Prescription Drug Benefit Manual, Chapter 9
- Medicare Managed Care Manual, Chapter 21
- Prescription Drug Benefit Manual, Chapter 5

Related Policies and Procedures/Desk References/Job Aides:
COMP203 – Medicare Compliance-Lines of Communication Policy and Procedure
National Delegation Policy and Procedure 106
National Delegation Policy and Procedure 107
Compliance/Ethics Complaints and Concerns Handling Policy
Routine Investigations Manual
Aetna Health Care Anti-Fraud Plan
Special Investigations Unit Policies and Procedures manual
Aetna’s Record Retention Policy
Aetna FDR Program Description
Multiple supplementary guides

REVIEW:

Accountable for Policy Maintenance: Nancy Mundy, Sr Director, Compliance/Meegan Johnson, Director, Compliance

Accountable for Implementation: John Wells, Medicare Compliance Officer

Approval Signature & Date:

Legal: Nicole Cerquitella, Medicare Legal Counsel 03/01/2017
Compliance: John Wells, Medicare Compliance Officer 03/08/2017

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<td>Defined MCO approval of Changes to Compliance Workplan</td>
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<tr>
<td>8/30/2013</td>
<td>3.0</td>
<td>Defined communication of workplan changes to Medicare Compliance Committee</td>
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<tr>
<td>1/13/2014</td>
<td>4.0</td>
<td>Updated for the following reasons: 2014 Readiness Checklist item of proactive reporting of FDR changes; CMS audit CAP for FDR annual audit plan addition; and annual update.</td>
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Medicare Compliance

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Review/Approval Date:

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Signature
Committee Co-Chairperson
Aetna Pharmacy Management Quality Oversight committee (APMQOC)

_3/29/2017__________________________
Approval Date
PURPOSE

The purpose of this document is to implement the relevant provisions of 42 C.F.R. § 422.503(b)(4)(vi) and 423.504(b)(4)(vi) and Chapter 9 of the PDBM, and Chapter 21 of the MMCM, which requires sponsors to implement an effective compliance program, including procedures for effective lines of communication and ensuring confidentiality between the Compliance Officer and the organization’s employees, managers, governing body, members of the MCC, and FDRs.

POLICY

Aetna and its Medicare Compliance Program will comply with all applicable federal and state laws and regulations regarding the establishment of a compliance program. Specifically, Medicare Compliance will adhere to standards for effective lines of communication and ensuring confidentiality between the MCO, members of the MCC, Aetna’s employees, managers and governing body, and Aetna’s FDRs. Such lines of communication will be accessible to all, be user-friendly, and allow for anonymous and confidential good faith reporting of potential or actual compliance issues as well as suspected or actual violations relating to the Medicare program. In addition, Aetna has adopted a policy of non-intimidation and non-retaliation and enforces a no-tolerance policy for retaliation or retribution for good faith reporting of compliance or FWA concerns. The processes defined within this policy may be modified by Aetna based upon the unique circumstances of specific plan contracts (e.g., MMP demonstration plans, etc.). The definitions/acronyms used within this policy are listed below.

DEFINITIONS/ACRONYMS

BOD – Board of Directors
CMS - Centers for Medicare & Medicaid Services
COC – Code of Conduct
FDR - First Tier, Downstream, and Related entity
FWA - Fraud, Waste, and Abuse
HPMS - Health Plan Management System
MA – Medicare Advantage
PROCEDURE

1. **Communications from the Medicare Compliance Officer**

   A. The MCO will communicate key initiatives and changes, including new and revised policies and procedures and updates to the Medicare Compliance Plan, to Medicare supporting employees through various Medicare Compliance communications which may include any combination of the following: Medicare Compliance Regulatory Alerts, Medicare Compliance intranet site (i.e., AetNet), training programs, verbal and written communications, and telephonic announcements.

   B. Aetna's AetNet includes information about the various methods available for reporting compliance issues and concerns (see Section 2. below), as well as for reporting potential FWA issues. In addition, the AetNet contains Aetna’s MCO contact information (e.g., MCO name, office location, etc.) and the Medicare Compliance Policies and Procedures.

   C. Medicare Compliance may periodically develop and post intranet-based communication (e.g., newsletters, etc.) to be accessed by employees. Such communications may include key reporting requirements and information about the various methods available for reporting.

   D. Medicare Compliance will distribute statutory, regulatory and sub-regulatory changes (including HPMS Memos) through a distribution and tracking tool. Distribution lists are maintained on an ongoing basis, and are verified at least annually to ensure communications are accurately directed. Business leads are expected to communicate guidance, as applicable, to relevant FDRs. Refer to New Guidance Distribution Desk Reference guide for more information.

   E. The MCO ensures the reporting of Medicare-related compliance issues on a regular basis to the MCC, Aetna Medicare senior management, Chief Ethics and Compliance Officer, the BOD or the Audit Committee of the BOD, as well as to any accountable business leads as necessary.

2. **Communicating with and Reporting to Medicare Compliance**

   As described in Aetna’s COC, employees, contingent workers, the BOD, and FDR employees are required to report suspected or detected noncompliance, and potential FWA.
To accommodate the various topics and to establish preferred communication methods, Aetna has developed various methods of reporting.

A. Aetna Medicare Compliance Reporting Mechanisms:
   1) Directly to the MCO: the name, office location, and contact information for Aetna’s MCO is displayed on the Medicare Compliance AetNet Site. The annual Business Conduct & Integrity Training directs to this intranet information, as well.
   2) Email correspondence to designated Medicare Compliance mailboxes
      a. MedicareCompliance@Aetna.com
      b. AskJohn@Aetna.com
   4) Medicare Compliance phone line: 215-775-6801 (May leave a message or an anonymous message)
   5) Medicare Compliance Subject Matter Experts: Medicare Compliance personnel are identified on the Medicare Compliance AetNet site for their subject matter expertise. Confidential e-mails or telephonic contacts may be directed to this staff. Additionally, reporting may occur during staff ongoing interactions with the associated business units as part of normal business operations.

B. Aetna hotline:
   Aetna has also established a toll-free hotline, the AlertLine®, which is accessible to all parties 24 hours a day/7 days a week for reporting of potential compliance and ethics issues and/or potential FWA.
   1) Aetna’s AlertLine®, provides for anonymous and confidential reporting (to the greatest extent possible).
   2) Periodically, “Core Compliance” provides the MCO with a summary of all Medicare related AlertLine®, cases. Such cases are typically reviewed and monitored by Medicare Compliance, working with Core Compliance. In the event that investigative actions are warranted, Medicare Compliance, as well as Core Compliance, maintains an active oversight role. Annually, Core Compliance presents case trends to the MCC.
   3) Aetna’s AlertLine® contact information is displayed throughout the enterprise, as well as on the AetNet, in Aetna’s COC, and in Compliance Training modules. AlertLine® allows for three ways to anonymously report; telephonically, by writing to: Corporate Compliance, P.O. Box 370205, West Hartford, CT 06137-0205 or via the AlertLine®, website at https://aetna.alertline.com.

C. Aetna SIU:
   Aetna’s SIU has established various reporting mechanisms to ensure that potential FWA can be easily reported by employees, contingent workers, the BOD, employees of FDRs, and members. Reporting can be initiated via an e.Service/ web-based form, e-mail or calling a hotline. Calls to the hotline are monitored regularly, and may be made anonymously. Aetna’s SIU and Medicare Compliance collaborate with other functional units (e.g., Agent Oversight, Investigative Services), as necessary. SIU activities are routinely reported by the SIU to the MCC.
D. No tolerance policy:
Each of the reporting methods and Aetna’s no-tolerance policy of intimidation and retaliation are publicized within Aetna through its intranet site and other modalities (e.g., compliance training, etc.). Parties who report potential Medicare Compliance issues, through the above resources, or by individual meetings, by phone or by email will be kept in confidence to the greatest extent possible.

3. Recording, Responding To, and Tracking Reports

A. Medicare Compliance will coordinate or respond to, assess and investigate to the extent warranted, all compliance questions and reports of suspected or detected noncompliance or potential FWA. Appropriate actions will be taken in accordance with Medicare Compliance Policy 202 - Risk Assessment, Auditing and Monitoring, and Issue Management Policy and Procedure.

B. Medicare Compliance ensures the recording and tracking of reports of suspected or detected noncompliance or potential FWA which may be used to identify trends and potential systemic issues.

C. FWA case details are maintained in accordance with Aetna’s Record Retention Policy and operationalized by Aetna’s SIU, Investigative Services, and/or Agent Oversight.

SOURCES/REFERENCES:

Regulatory References:
42 CFR 422.503(b)(4)(vi)(D)
42 CFR 423.504(b)(4)(vi)(D)
Prescription Drug Benefit Manual, Chapter 9
Medicare Managed Care Manual, Chapter 21

Related Policies and Procedures/Desk References/Job Aides:
Aetna Health Care Anti-Fraud Plan
Special Investigations Unit Policies and Procedures manual
Aetna’s Record Retention Policy
New Guidance Distribution Desk Reference

REVIEW:

Accountable for Policy Maintenance: Nancy Mundy, Sr Director, Compliance/Meegan Johnson, Director, Compliance
Accountable for Implementation: John Wells, Medicare Compliance Officer
DEPARTMENT: Medicare Compliance

POLICY #: COMP 203

Version #: 5.0

POLICY TITLE: Medicare Compliance - Lines of Communications Policy and Procedure

EFFECTIVE DATE: 01/21/2013

Approval Signature & Date:
Legal: Nicole Cerquitella, Medicare Legal Counsel 03/02/2017
Compliance: John Wells, Medicare Compliance Officer 02/28/2017

Review & Revision History:
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Review/Approval Date:
3/29/2017

Signature
Committee Co-Chairperson
Aetna Pharmacy Management Quality Oversight committee (APMQOC)

3/29/2017
Approval Date
PURPOSE

Pursuant to 42 C.F.R. §§ 422.503(b)(4)(vi), and 423.504(b)(4)(vi), Chapter 9 of the PDBM, and Chapter 21 of the MMCM Aetna, as a Medicare Advantage organization and Part D plan sponsor, is required to have an effective compliance program. The purpose of this document is to set forth Aetna’s policy and procedures for facilitating compliance and FWA training and code of conduct distribution.

POLICY

Aetna Medicare Compliance will comply with all applicable federal and state laws and regulations regarding the establishment of a compliance plan. Specifically, Medicare Compliance will establish, implement and provide effective compliance and FWA training including code of conduct distribution to all Aetna Medicare supporting employees (including CEO, managers, etc.), governing bodies (e.g. BOD), and FDRs. Aetna’s training modules are reviewed and updated, at least annually, and more often if needed to reflect changes to related laws, regulations, policy, or guidance. The processes defined within this policy may be modified by Aetna based upon the unique circumstances of specific plan contracts (e.g., MMP demonstration plans, etc.). The definitions/acronyms used within this policy are listed below.

DEFINITIONS/ACRONYMS

AHIP - America’s Health Insurance Plans
BCI – Business, Conduct & Integrity
BOD – Board of Directors
CEO - Chief Executive Officer
COC – Code of Conduct
CMS - Centers for Medicare & Medicaid Services
DMEPOS - Durable Medical Equipment, Prosthetics, Orthotics, and Suppliers
FDR - First Tier, Downstream, and Related entities
FWA - Fraud, Waste, and Abuse
MA – Medicare Advantage
MLN - Medicare Learning Network
PROCEDURE

1. **Aetna Employees**

   A. Aetna’s employees are provided general compliance and FWA training through the Aetna BCI Training process. In addition, individuals who are employed by other legal entities may be classified as contingent workers who also receive Aetna BCI Training. Aetna’s BCI training must be completed within 90 days of hire and annually thereafter.

   B. The BCI Training is reviewed annually for any needed updates. Off-cycle updates are made to address significant changes to laws, regulations, policy, and guidance, as needed.

   C. The identification of employees supporting Aetna’s Medicare products is made by Aetna Managers through the eService Contractual Identification tool at the time of hire then reviewed and updated periodically.

   D. The BCI Training is delivered through the online Aetna Learning Center. Employees are instructed to complete the training initially upon hire and then annually through system-generated e-mail notifications (i.e., initial notices and then subsequent reminders). Aetna’s COC is part of the BCI Training program and includes the completion of an acknowledgment of receipt, review of, and compliance with the Code of Conduct in order to receive full credit for the BCI Training. In addition, Aetna’s Medicare Compliance Department Policies and Procedures are part of the BCI Training.

   E. BCI Training completion is monitored. Disciplinary actions are taken, as needed, to enforce completion of this required training.

   F. Training records are maintained for a period of no less than ten (10) years and will include time, attendance, topic, certificates of completion (if applicable), and test scores of any tests administered.

2. **Aetna’s Board of Directors**

   Aetna’s BOD completes a general compliance and FWA training within 90 days of appointment and then annually thereafter. The training materials are supplied to the Corporate Secretary who delivers them together with an acknowledgment form to each board member. Upon completion of the course, Medicare Compliance collects the completed acknowledgments from the Corporate Secretary. The acknowledgments include confirmation of COC awareness, completion of Aetna’s BCI Trainings, agreement to comply with these standards, and disclosure of any conflict of interest.
3. FDR Employees

A. General Compliance and Fraud, Waste, and Abuse Training:

1) In accordance with CMS requirements, Aetna has criteria to determine which entities are FDRs utilizing an FDR Classification process, as needed. See the Aetna FDR Program Description and the Aetna FDR Classification Guidelines for more information.

2) Applicable FDR employees are required to complete the below CMS trainings within 90 days of hire or contracting and at least annually thereafter (i.e., any time between January 1 – December 31 of any given contract year). CMS updates these trainings annually for FDR use. FDRs’ applicable employees are determined through Aetna’s designation of positions in conjunction with discussions with FDRs, as necessary.

   i. Combating Medicare Parts C and D Fraud, Waste, and Abuse Training; and
   ii. Medicare Parts C and D General Compliance Training.

3) FDRs have three options for ensuring that their applicable employees have satisfied the training requirements:

   i. Completion directly on CMS’ Medicare Learning Network (MLN) site which generate certificates of completion, or
   ii. Download and incorporate both of CMS’ training modules, without modification except for formatting, into internal training systems, or
   iii. Incorporate content of CMS training modules into written documents, without modification except for formatting, for providers (e.g., Provider Guides, Participation Manuals, Business Associate Agreements, etc.).

4) FDRs are deemed to have met the FWA training requirements through enrollment into Parts A or B of the Medicare program or through accreditation as a supplier of DMEPOS. However, deemed FDRs are not exempt from the general compliance training requirements.

5) Aetna provides notices to FDRs of the CMS training requirements through various mechanisms such as newsletters, e-mail notifications, fax blasts, website/web portal postings, etc. In addition, Aetna communicates general compliance information through the Aetna COC and Medicare Compliance Department Policies and Procedures dissemination to FDRs within 90 days of contracting, with updates as necessary, and annually thereafter.

6) FDRs are required to retain evidence of training completion (e.g., training logs, employee certifications, etc.) for a period of no less than ten (10) years, and to make this evidence available to Aetna and/or CMS, upon request (i.e., for FDR audits, etc.).

7) See the Aetna FDR Program Description for more information.

B. FDR attestations:

FDRs may be asked to complete and submit to Aetna an annual attestation which is a self-assessment of training completion.
4. **Medicare Enrollees**

   Aetna provides education to enrollees about the identification and reporting of FWA through various mechanisms such as website postings, etc.

5. **Specialized Medicare Compliance Training**

   A. Additional, specialized, or refresher training may be delivered by either a business area, Medicare Compliance, or both, depending on the training objective.

   B. Operational areas deliver new hire training, training when there are significant changes to procedures, or refresher training when there is an upcoming annual event (e.g., Annual Enrollment Period). Medicare Compliance may develop and deliver specialized focused training in the event that there are issues or trends that have been identified. Topics covered and required attendees will be defined on a case by case basis.

   C. Examples of specialized training that may be developed include:
   1) Handling Complaints, Grievances and Appeals
   2) Marketing to Medicare beneficiaries
   3) Medicare Regulatory Guidance Distribution & Validation process
   4) CMS Requirements for FDRs
   5) OIG & SAM Exclusion Screenings
   6) FDR Compliance Program Requirements

**SOURCES/REFERENCES:**

**Regulatory References:**

42 CFR 422.503(b)(4)(vi)(C & D)
42 CFR 423.504(b)(4)(vi)(C & D)
42 CFR 422.2274(b)
42 CFR 423.2274(b)

Prescription Drug Benefit Manual, Chapter 9
Medicare Managed Care Manual, Chapter 21

**Related Policies and Procedures/Desk References/Job Aides:**

Aetna FDR Program Description
Aetna FDR Classification Guidelines

**REVIEW:**

Accountable for Policy Maintenance: Nancy Mundy, Sr Director, Compliance/Meegan Johnson, Director, Compliance
Accountable for Implementation: John Wells, Medicare Compliance Officer
## Medicare Compliance

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### Approval Signature & Date:
- Legal: Nicole Cerquitella, Medicare Legal Counsel 03/09/2017
- Compliance: John Wells, Medicare Compliance Officer 03/01/2017

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