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Medicare

DEPARTMENT: Medicare Compliance	POLICY #: COMP 201	Version #: 6.0	EFFECTIVE DATE: 01/21/2013
POLICY TITLE: Creation and Maintenance of Medicare Compliance Policies, Procedures and other Compliance Documents			REVISION DATE: 04/11/2018 Last Modified By: Cheryl Hayes
PREPARED BY: Christina F. Melton	PRODUCT: Part C and Part D program (e.g., MA, PDP, MMP, etc.)	MARKET: All	NEXT REVIEW DATE: 04/11/2019

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

Aetna has established written policies and procedures, including a Medicare Compliance Plan to describe Aetna's compliance and ethical standards and practices, and its commitment to comply with all applicable federal and state laws and regulations. The Medicare Compliance Plan and other related documents 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

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PDBM - Prescription Drug Benefit Manual
PDP – Prescription Drug Plan

PROCEDURE

1. Creation of New Medicare Compliance Policies and Procedures

Medicare Compliance may need to develop and implement a policy and procedure to address new or revised laws, regulations, or program requirements. When a new policy is drafted:

A. The Medicare Compliance Policy and Procedure Template is used. Desktop guides, or checklists, 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. The draft policy will be reviewed and approved by the Medicare Compliance staff responsible for the affected area.

D. The draft policy may be shared with other Medicare Compliance staff and/or business partners for review. This review is to ensure that there are no conflicts to other business or compliance policies and procedures.

E. The draft policy will be reviewed by the MCO or his or her designee for comments and feedback. Medicare Legal Counsel reviews and approves policy content.

F. Updates will be made to the draft policy. 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. Revisions may be made based upon legal, regulatory, or program changes. 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 reviews and approves policy content.

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

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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 and other related documents (Code of Conduct and Medicare Compliance Plan), are maintained on Aetna's intranet location, which is accessible on an ongoing basis to all Medicare supporting employees.
B. Medicare Compliance Policies and Procedures and the Aetna Code of Conduct are communicated to employees who support Aetna's Medicare business within 90 days of hire and annually thereafter through Aetna's BCI training.
C. Policy changes are circulated through various mechanisms: staff meetings; MCC presentations; intranet postings, etc.

4. Record Retention

When a new or updated policy is finalized, obsolete policies are archived in accordance with Aetna's Records Retention Schedule and CMS requirements.

5. Other Related Compliance Documents

A. Aetna Code of Conduct:
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. Medicare Compliance participates, as needed, in the company's ad hoc or periodic review and update of the COC. The COC is approved by Aetna's BOD when material changes are made to the content.

B. Aetna Medicare Compliance Plan:
The Aetna Medicare Compliance Plan is a document that provides an overview of Aetna's Medicare Compliance Program. Aetna's Medicare Compliance Program meets 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. Medicare Compliance maintains the Aetna Medicare Compliance Plan and it is reviewed at least annually.

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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: Cheryl Hayes, Sr. Compliance Lead/Meegan Johnson, Sr. Director, Compliance
Accountable for Implementation: John Wells, Medicare Compliance Officer(MCO)

Approval Signature & Date:

Legal: Nicole Cerquitella, Medicare Legal Counsel 04/06/2018
Compliance: John Wells, Medicare Compliance Officer 04/11/2018

Review & Revision History:

Date	Revision No.	Reason for Change
01/21/2013	1.0	Updated as part of P&P regulatory update project; Supersedes Policy 121
02/07/2014	2.0	Annual review and update
02/12/2015	3.0	Annual review and update
02/09/2016	4.0	Annual review and update
03/09/2017	5.0	Annual review and update
04/11/2018	6.0	Annual review and update

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Review/Approval Date:

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Scott Spradlin, DO, FACP, FACOI
Committee Co-Chairperson
Aetna Pharmacy Management Quality Oversight committee (APMQOC)

_05/30/2018_____
Approval Date

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DEPARTMENT: Medicare Compliance	POLICY #: COMP 202	Version #: 8.0	EFFECTIVE DATE: 01/21/2013
POLICY TITLE: Compliance Risk Assessment, Auditing, Monitoring and Issue Management Policy and Procedure			REVISION DATE: 04/11/2018 Last Modified By: Cheryl Hayes
PREPARED BY: Christina F. Melton	PRODUCT: Part C and Part D program (e.g., MA, PDP, MMP, etc.)	MARKET: All	NEXT REVIEW DATE: 04/11/2019

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 Program and Work Plan(s). In order to identify potential or actual compliance and/or FWA risks, Aetna has established and maintains a process to audit and monitor its Medicare functions, including those performed by FDRs. This includes monitoring and auditing for compliance with Medicare regulatory and sub-regulatory guidance, contractual requirements, applicable federal and state laws, and adherence to Aetna's policies and procedures. Aetna ensures prompt response when risks are identified. 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
CMS - Centers for Medicare & Medicaid Services

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CTM – Complaints Tracking Module
FDR - First Tier, Downstream, and Related entities
FWA – Fraud, Waste, and Abuse
HPMS – Health Plan Management System
MA – Medicare Advantage
MCC – Medicare Compliance Committee
MCO - Medicare Compliance Officer
MMCM - Medicare Managed Care Manual
MMP – Medicare-Medicaid Plan
NBI MEDIC - National Benefit Integrity Medicare Drug Integrity Contractor
OIG – U.S. Department of Health & Human Services' Office of Inspector General
PBM – Pharmacy Benefit Manager
PDBM - Prescription Drug Benefit Manual
PDP – Prescription Drug Plan
SAM - General Services Administration's System for Award Management
SIU – Special Investigations Unit

PROCESSES

1. System to Identify Compliance Risks

Medicare Compliance coordinates with other internal 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.

In addition to operational business area risks, a First Tier Risk Assessment is completed. The assessment includes all First Tier entities servicing Aetna Medicare contracts. First Tier entities may be ranked and scored at the First Tier Type (i.e. claim delegates, providers, risk adjustment vendors, etc.) and/or First Tier entity level. The highest risk entities are prioritized for targeted evaluation 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 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 may also include additional activities in response to audit and/or monitoring results, such as conducting follow up reviews of areas found to be non-compliant. Follow up reviews are conducted 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. See the supplementary *Aetna FDR Program Description* for additional details.

Medicare Compliance collaborates with business partners for completion of these activities, including the audits, monitors or follow up reviews, where applicable.

B. Execution of the Work Plan:

The Medicare Compliance staff has access to Aetna personnel, documents, legal counsel, operational units, and FDRs as needed to support the Work Plan activities.

The activities directed by the Work Plan are led or overseen by Aetna Medicare Compliance to ensure compliance with Medicare regulations and other applicable requirements. The 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 policies 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 monitoring and audits are reflected in standard reports that include objectives, scope and methodology, findings, recommendations, and include key stakeholders during distribution, as applicable.

The MCO or designee(s) provide updates on the 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 a subset thereof. 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 will be audited by a third party at least annually. Results of the Compliance Program audit are shared with the MCO, the Aetna 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 and SAM sanction and debarment screenings of employees, temporary employees, consultants, governing body members and First Tier entities. These areas maintain their own policies and procedures to ensure pre-hire/contracting and monthly screening occur and 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. 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* which identifies the various methods available for reporting FWA concerns to Medicare Compliance and the SIU. In addition, Medicare Compliance, including the MCO, is accessible to the SIU 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 the *Special Investigations Unit Policies and Procedures* manual.

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. 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, Agent Oversight), as needed. 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.

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 will conduct a timely, reasonable inquiry into evidence of misconduct, non-compliance, and/or suspected FWA related to payment or delivery of items or services. Aetna is committed to initiating investigations into potential compliance issues (including misconduct) or suspected FWA in a timely manner, not later than 14 calendar days from identification. Three main systems receive and investigate these potential issues as described below and outlined in COMP 203 – *Medicare Compliance Lines of Communications Policy and Procedure*.

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. Per *Aetna's Compliance/Ethics Complaints and Concerns Handling Policy,* Aetna ensures prompt and complete review and/or investigation of all compliance and ethics matters received through the various reporting channels. Investigations are typically initiated within 2 business days. A database (e.g., TrakEnterprise) is used to record compliance and ethics concerns received through these mechanisms.
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. A system (e.g., CaseTracker) is used to record potential FWA concerns received through these mechanisms.

3) Aetna Medicare Compliance: Issues are received by, identified by, or directed to the Aetna Medicare Compliance team through a variety of available mechanisms. 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 after the date that the potential issue was identified. A system (e.g., eGRC) is used to record concerns received through these mechanisms.

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 on issue investigations.

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 CAPs for each issue. CAPs are designed to correct the underlying problem, prevent future instances or continued non-compliance, 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) Additional CAs may include overpayment recovery, payment suspension, Prescription Drug Event correction/deletion, and other actions up to and including contract termination. 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) Issues of non-compliance require remediation. CAPs are reviewed by Aetna Medicare Compliance to determine the reasonableness of the plan of action. In addition, Aetna Medicare Compliance tracks the completion of the CAP to resolution.
4) CAPs to address non-compliance by an FDR are monitored by the appropriate business area/oversight committee, as applicable. Medicare Compliance sponsors a FDR Oversight Committee that oversees FDR CAPs, high risk FDRs, etc. 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 through review of supportive documentation 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

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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 key information proactively (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 PBM contract change occurring within less than 60 days, Aetna must notify CMS 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
- 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
Compliance/Ethics Complaints and Concerns Handling Policy
Aetna Health Care Anti-Fraud Plan
Special Investigations Unit Policies and Procedures manual
Aetna's Record Retention Policy

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Aetna FDR Program Description
Multiple supplementary guides

REVIEW:

Accountable for Policy Maintenance: Cheryl Hayes, Sr. Compliance Lead/Meegan Johnson, Sr. Director, Compliance

Accountable for Implementation: John Wells, Medicare Compliance Officer

Approval Signature & Date:

Legal: _Nicole Cerquitella, Medicare Legal Counsel_ 04/06/2018
Compliance: _John Wells, Medicare Compliance Officer_ 04/11/2018

Review & Revision History:

Date	**Revision No.**	**Reason for Change**
01/21/2013	1.0	Updated as part of P&P regulatory update project; Supersedes Policy 114
7/01/2013	2.0	Defined MCO approval of Changes to Compliance Workplan
8/30/2013	3.0	Defined communication of workplan changes to Medicare Compliance Committee
1/13/2014	4.0	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.
2/12/2015	5.0	Annual review and update
2/9/2016	6.0	Annual review and update
03/08/2017	7.0	Annual review and update
04/11/2018	8.0	Annual review and update

Review/Approval Date:

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Scott Spradlin, DO, FACP, FACOI
Committee Co-Chairperson
Aetna Pharmacy Management Quality Oversight committee (APMQOC)

_05/30/2018_____
Approval Date

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DEPARTMENT: Medicare Compliance	POLICY #: COMP 203	Version #: 6.0	EFFECTIVE DATE: 01/21/2013
POLICY TITLE: Medicare Compliance - Lines of Communication Policy and Procedure			REVISION DATE: 4/11/2018 Last Modified By: Cheryl Hayes
PREPARED BY: Christina F. Melton	PRODUCT: Part C and Part D products (e.g., MA, PDP, MMP, etc.)	MARKET: All	NEXT REVIEW DATE: 04/11/2019

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 will comply with all applicable federal and state laws and regulations regarding the establishment of a compliance program, including 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. The lines of communication will be accessible to all, be user-friendly, and allow for anonymous and confidential good faith reporting. This reporting includes potential or actual compliance issues and/or FWA 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

BCI – Business, Conduct & Integrity
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

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MCC - Medicare Compliance Committee
MCO - Medicare Compliance Officer
MMCM - Medicare Managed Care Manual
MMP – Medicare-Medicaid Plan
PDBM - Prescription Drug Benefit Manual
PDP – Prescription Drug Plan
SIU—Special Investigations Unit

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. This may occur through Medicare Compliance Regulatory Alerts, Medicare Compliance intranet site, training programs, verbal and written communications, and telephonic announcements.
B. Aetna's intranet includes information about the methods available for reporting compliance and FWA issues and concerns. In addition, Medicare Compliance's intranet contains the Aetna's MCO contact information (e.g., MCO name, office location, etc.), the Medicare Compliance Policies and Procedures, and the Medicare Compliance Plan, as well as a link to the Aetna Code of Conduct.
C. Medicare Compliance may periodically develop and post intranet-based communications (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. Refer to *New Guidance Distribution Desk Reference* guide for more information. Business leads are expected to communicate guidance, as applicable, to relevant FDRs.
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, the BOD, and FDR employees are required to report suspected or detected noncompliance, and potential FWA. Aetna has developed

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various methods of communicating with Medicare Compliance, including reporting compliance/FWA concerns.

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 intranet. The Aetna BCI 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 an anonymous message)
   5) Medicare Compliance Subject Matter Experts: Medicare Compliance personnel are identified on the Medicare Compliance intranet. 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, the MCO is provided with a summary of all Medicare related AlertLine® cases. Cases are reviewed and monitored by Medicare Compliance when appropriate. All cases are investigated. Medicare Compliance may collaborate or lead investigations with other Aetna departments. Case trends are annually reported to the MCC.
   3) Aetna's AlertLine® contact information is displayed throughout the enterprise, as well as on the intranet, in Aetna's COC, and in compliance training modules. AlertLine® allows for three ways to anonymously report; by calling 1-888-891-8910, by writing to: Corporate Compliance, P.O. Box 370205, West Hartford, CT 06137-0205 or online at https://aetna.alertline.com.

C. Aetna SIU:

   Aetna's SIU has established and monitors various reporting mechanisms to ensure that potential FWA can be easily reported by employees, the BOD, employees of FDRs, and members. Reporting can be initiated via the intranet, e-mail or calling a hotline. Calls to the hotline 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 to the MCC.

D. No tolerance policy:

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Aetna has a no-tolerance policy for intimidation and retaliation which is publicized on the intranet and other communications (e.g., compliance training, Aetna Code of Conduct, etc.). Parties who report potential Medicare Compliance issues are kept in confidence to the greatest extent possible.

3. Recording, Responding To, and Tracking Reports

A. Medicare Compliance ensures that compliance questions and reports of suspected or detected noncompliance or potential FWA are responded to appropriately. This may include oversight and coordination with other areas to investigate reported concerns. 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. This may be used to identify trends and potential systemic issues.
C. Reported case details are maintained in accordance with Aetna's Record Retention Policy.

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
Medicare Compliance Policy 202 – Risk Assessment, Auditing and Monitoring, and Issue Management Policy and Procedure
New Guidance Distribution Desk Reference

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REVIEW:

Accountable for Policy Maintenance: Cheryl Hayes, Sr. Compliance Lead, Compliance/Meegan Johnson, Sr. Director, Compliance
Accountable for Implementation: John Wells, Medicare Compliance Officer

Approval Signature & Date:

Legal: : Nicole Cerquitella, Medicare Legal Counsel 04/06/2018
Compliance: John Wells, Medicare Compliance Officer 4/11/2018

Review & Revision History:

Date	Revision No.	Reason for Change
01/21/2013	1.0	Updated as part of P&P regulatory update project, Supersedes Policy 116
02/07/2014	2.0	Annual review and update
2/12/2015	3.0	Annual review and update
2/9/2016	4.0	Annual review and update
03/02/2017	5.0	Annual review and update
04/11/2018	6.0	Annual review and update

Review/Approval Date:

Scott Spradlin, DO, FACP, FACOI
Committee Co-Chairperson
Aetna Pharmacy Management Quality Oversight committee (APMQOC)

05/30/2018
Approval Date

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Medicare

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POLICY TITLE: **Medicare Compliance and Fraud, Waste, and Abuse Training Policy and Procedure**			REVISION DATE: 04/11/2018 **Last Modified By:** Cheryl Hayes
PREPARED BY: Christina F. Melton	**PRODUCT:** Part C and Part D products (e.g., MA, PDP, MMP, etc.)	**MARKET:** All	**NEXT REVIEW DATE:** 04/11/2019

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, including implementation of effective compliance and FWA training. The training will include COC distribution to all Aetna Medicare supporting employees, governing bodies, 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

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
MMCM - Medicare Managed Care Manual
MMP – Medicare-Medicaid Plan

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PDBM - Prescription Drug Benefit Manual
PDP – Prescription Drug Plan
SAM – General Services Administration's System of Award Management

PROCEDURE

1. Aetna Employees

A. Aetna Medicare supporting employees are identified by Aetna Managers through the eService Contractual Identification tool. Periodically, Aetna Managers are reminded to review their employees to ensure identification of Medicare supporting individuals.
B. Aetna Medicare supporting employees are provided general compliance and FWA training through the Aetna BCI Training process. Aetna's COC and Medicare Compliance Policies and Procedures are distributed through the BCI Training. Aetna's BCI training must be completed within 90 days of hire and annually thereafter.
C. Medicare Compliance participates, as needed, in the Company's annual or periodic review of the BCI Training. Updates can be made to address significant changes to laws, regulations, policy, and guidance, as needed.
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).
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 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. Medicare Compliance collects the completed acknowledgments from the Corporate Secretary. The acknowledgments include confirmation of COC awareness, completion of general compliance and FWA training, 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. See the *Aetna FDR Program Description* and the *Aetna FDR Classification Guidelines* for more information.

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2) Applicable FDR employees are required to complete the below CMS trainings within 90 days of hire or contracting and each calendar year thereafter. FDRs' applicable employees are determined through Aetna's designation of positions in conjunction with discussions with FDRs, as necessary. CMS maintains and updates these trainings for FDR use.
    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 the Aetna COC and Medicare Compliance Policies and Procedures 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) Individuals who are employed by FDRs may have access to Aetna's system and be classified as contingent workers. Contingent workers have access to Aetna's BCI Training, which includes the CMS modules, Aetna's COC and Aetna's Medicare Compliance Policies and Procedures
8) See the *Aetna FDR Program Description* for more information.

B. FDR attestations:
FDRs are requested 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, mailings, etc.

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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. Examples of specialized training that may be developed include:
    - Medicare Regulatory Guidance Distribution & Validation process
    - CMS Requirements for FDRs

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
CY 2015 Final Rule CMS–4159–F published May 23, 2014

Related Policies and Procedures/Desk References/Job Aides:
Aetna FDR Program Description
Aetna FDR Classification Guidelines

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REVIEW:

Accountable for Policy Maintenance: Cheryl Hayes, Sr. Compliance Lead, Compliance/Meegan Johnson, Sr. Director, Compliance
Accountable for Implementation: John Wells, Medicare Compliance Officer

Approval Signature & Date:

Legal: Nicole Cerquitella, Medicare Legal Counsel 04/06/2018
Compliance: John Wells, Medicare Compliance Officer 4/11/2018

Review & Revision History:

Date	**Revision No.**	**Reason for Change**
01/21/2013	1.0	Updated as part of P&P regulatory update project; Supersedes Policy 114
02/07/2014	2.0	Updated to include BCI Training usage; annual review and update
02/12/2015	3.0	Annual review and update
02/09/2016	4.0	Annual review and update and revision for CMS changes to FDR trainings via Final Rule and sub-regulatory guidance
03/09/2017	5.0	Annual review and update
04/11/2018	6.0	Annual review and update

Review/Approval Date:

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Scott Spradlin, DO, FACP, FACOI
Committee Co-Chairperson
Aetna Pharmacy Management Quality Oversight committee (APMQOC)

_05/30/2018_____
Approval Date