First Tier, Downstream, and Related Entities ("FDR") Medicare Compliance Program Guide

March 2015
I. Introduction – Aetna’s Medicare Compliance Program

Aetna’s reputation as an industry leader depends on our ability to deliver on our promises. For more than 160 years, we have been guided by the highest standards of integrity. Our relationships with our customers, business partners and suppliers are built on trust earned over time and through experience. Each day we must remember our commitment to do the right thing for the right reason and keep the people we serve at the center of everything we do. When we act with integrity, we are living The Aetna Way.

Our Medicare Compliance Program helps us serve our members ethically

We’re committed to practicing business in an ethical manner. Our Medicare Compliance Program is designed to:

- Reduce or eliminate fraud, waste, and abuse
- Make sure we comply with applicable laws, rules and regulations
- Reinforce our commitment to compliance

We use external entities to bring our members cost-effective healthcare solutions

Aetna Health Inc., Aetna Life Insurance Company and affiliates (Aetna) offer Medicare Advantage and Medicare prescription drug plans (collectively, “Medicare Plans”). We contract with several external individuals and entities as a cost effective and efficient way of providing administrative and healthcare services. Some of the services provided by external entities are services that we are required to perform under our contracts with CMS. The Centers for Medicare and Medicaid Services (CMS) refer to these entities as First Tier, Downstream, and Related entities (FDRs).

You’ll find specific requirements in this document

CMS also requires that Aetna’s FDRs fulfill specific Medicare Compliance Program requirements. We describe these requirements in this document. The Code of Federal Regulations (CFR) outlines these Medicare Compliance Program requirements and they are specifically defined by CMS in the January 11, 2013 release of the Compliance Program Guidelines found in Chapter 21 of the Medicare Managed Care Manual and Chapter 9 of the Prescription Drug Benefit Manual (Manual), which are identical.

It is important for you to follow these requirements

You received this guide because we’ve identified you as a First Tier Entity. This means that you must comply with these requirements.

II. What’s an FDR?

We use the current CMS definitions to define First Tier, Downstream, and Related Entities:

First Tier Entity is any party that enters into a written arrangement, acceptable to CMS, with a Medicare Advantage Organization or Part D plan sponsor or applicant to provide administrative
services or healthcare services to a Medicare eligible individual under the Medicare Advantage program or Part D program. (See, 42 C.F.R. §§ 422.500 & 423.501).

**Downstream Entity** is any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the Medicare Advantage benefit or Part D benefit, below the level of the arrangement between a Medicare Advantage Organization or applicant or a Part D plan sponsor or applicant and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services. (See, 42 C.F.R. §§ 422.500 & 423.501).

**Related Entity** means any entity that is related to a Medicare Advantage Organization or Part D sponsor by common ownership or control and:

1. Performs some of the Medicare Advantage Organization or Part D plan Sponsor’s management functions under contract or delegation; or

2. Furnishes services to Medicare enrollees under an oral or written agreement; or

3. Leases real property or sells materials to the Medicare Advantage Organization or Part D plan Sponsor at a cost of more than $2,500 during a contract period.

(See, 42 C.F.R. §§ 422.500 & 423.501).

**FDRs providing healthcare services**
The Medicare Compliance Program requirements described in this guide apply to healthcare providers contracted with Aetna to participate in our Medicare Plan network. This includes physicians, hospitals and other provider types. Here are the reasons why:

- First, Medicare Advantage (MA) regulations and CMS rules clearly state that providers contracted with Aetna to provide healthcare services to our Medicare members are “First Tier Entities.”

- Second, Chapter 9 of the Manual lists “healthcare services” as an example of the types of functions that a third party can perform that relates to an MA organization’s contract with CMS. This would give third parties “First Tier Entity” status. (See last bullet point in the Manual, Chapter 9 § 40.) So, these Medicare Compliance Program requirements apply to providers that actually deliver healthcare services to our Medicare members.

- Third, CMS provides a chart in the Manual, Chapter 9 § 40 showing that entities providing health services and hospital groups are first tier entities. So, if we contract with a hospital group and don’t have direct contracts with the group’s hospitals and other providers, the hospitals and providers are “Downstream Entities.” This means that the hospital group is a “First Tier Entity,” and must comply and make sure its
Downstream Entities comply with the CMS compliance program requirements in this guide.

**FDRs providing administrative services**
The Medicare Compliance Program requirements also apply to entities with which we contract to perform administrative service functions relating to our Medicare Advantage or Medicare Part D contracts with CMS. Some examples of administrative service functions include:

- Claims processing
- Patient management
- Credentialing*

*Under our Medicare Advantage contract with CMS, we’re required to credential healthcare providers that participate in our Medicare Plan network. We contract with entities to perform these credentialing services on our behalf under a delegation agreement. CMS considers these delegated credentialing entities to be First Tier Entities. CMS identifies delegated credentialing entities as First Tier Entities in the Manual, Chapter 11 § 100.5.

Other examples of FDRs include delegates, agents, broker organizations, pharmacies and other individuals, entities, vendors or suppliers contracted with Aetna to provide administrative and/or healthcare services for our Medicare Plans. You can find more information in the Manual, Chapter 9 § 40, including the Stakeholder Relationship Flow Charts.

**III. FDR Medicare Compliance Program & attestation requirements**

It’s important that our FDRs are in compliance with applicable laws, rules and regulations. Although we contract with FDRs to provide administrative and/or healthcare services for our Medicare Plans, in the end, we’re responsible for fulfilling the terms and conditions of our contract with CMS and meeting applicable Medicare program requirements.

**Compliance program requirements**
First Tier Entities are responsible for making sure that their Downstream Entities comply with applicable laws and regulations, including the requirements in this guide. As a First Tier Entity, you/your organization and all of your Downstream Entities (if applicable) must comply with Medicare Compliance Program requirements. This guide summarizes your Medicare Compliance Program responsibilities. Please review it to make sure that you have internal processes to support your compliance with these requirements each calendar year. These Medicare Compliance Program requirements include, but are not limited to:

- Fraud, Waste and Abuse (“FWA”) training, general compliance training and Code of Conduct/compliance policy distribution
B. Exclusion list screenings
C. Reporting FWA and compliance concerns to Aetna
D. Offshore operations & CMS reporting
E. Specific federal and state compliance obligations
F. Monitoring and auditing of First Tier, Downstream and Related Entities

Also, see the “Toolbox of Resources for FDRs” at the end of this guide. It may help you with meeting these requirements.

What may happen if you don’t comply
If our FDRs fail to meet these Medicare Compliance Program requirements, it may lead to:
- Development of a corrective action plan
- Retraining
- Termination of your contract and relationship with Aetna

Our actions in response to a First Tier Entity’s non-compliance will depend on the severity of the compliance issue. If a First Tier Entity identifies areas of non-compliance (e.g., refusal of an employee to complete the required FWA training), the First Tier Entity must take prompt action to fix the issue and prevent it from happening again.

Attestation requirements
You must to maintain evidence of your compliance with these Medicare Compliance Program requirements (e.g., employee training records, CMS certificate of FWA training completion, etc.) for no less than 10 years. Also, each year, an authorized representative from your organization must attest to your compliance with the Medicare Compliance Program requirements described in this guide. The authorized representative is an individual who has responsibility directly or indirectly for all:

- Employees
- Contracted personnel
- Providers/practitioners
- Vendors who provide healthcare and/or administrative services for Aetna’s Medicare Plans

This could be your Compliance Officer, Chief Medical Officer, Practice Manager/Administrator, Provider, an Executive Officer or similar related positions.

You may be asked to provide evidence of compliance
In addition to completing an attestation, Aetna and/or CMS may request that you provide evidence of your compliance with these Medicare Compliance Program requirements. This is for monitoring/auditing purposes.
We take these responsibilities very seriously. If you have questions or concerns about these Medicare Compliance Program requirements, just contact your Aetna Relationship Manager. What follows is a description of each Medicare Compliance Program requirement.

**A. Fraud, Waste and Abuse ("FWA") training, general compliance training and Code of Conduct/compliance policy distribution**

**FWA and general compliance training**
As a First Tier Entity, you/your organization must provide FWA and general compliance training to all your employees and Downstream Entities assigned to provide administrative and/or healthcare services for our Medicare Plans. To comply with this requirement, you can use the [CMS Medicare Parts C & D Fraud, Waste, and Abuse Training and General Compliance Training](#). You can also substitute an equivalent version to satisfy these training requirements.

**Compliance training requirements**
Regardless of the method used, the training must be completed:
- Within 90 days of initial hire or the effective date of contracting
- At least annually thereafter

Also, you must maintain evidence of training completion. Evidence of completion may be in the form of attestations, training logs, or other means determined by you to best represent fulfillment of your obligations. For convenience, there are certificates of completion included on the last slides of the [CMS Medicare Parts C & D Fraud, Waste, and Abuse Training and General Compliance Training](#).

The only exception to this training requirement is if you/your organization is “deemed” to have met the FWA certification requirements through enrollment into Medicare Parts A or B of the Medicare program or though accreditation as a supplier of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). Those parties deemed to have met the FWA training through enrollment into the CMS Medicare Program don’t need to complete *Part 1: Medicare Parts C and D Fraud, Waste, and Abuse Training*. But, they’re still obligated to complete *Part 2: Medicare Parts C & D Compliance Training*.

You can find the training requirements and information regarding deemed status at:

- 42 C.F.R. § 422.503(b)(4)(vi)(C) for Medicare Advantage
- 42 C.F.R. § 423.504(b)(4)(vi)(C) for Part D
- Manual, Chapter 9 § 50.3
You must give your employees Standards of Conduct

Your organization must also provide either Aetna’s Code of Conduct (COC) and Medicare Compliance Policies or your own comparable COC/Compliance Policies (collectively, “Standards of Conduct”) to all employees and Downstream Entities who provide administrative and/or healthcare services for our Medicare Plans. You must distribute Standards of Conduct:

- Within 90 days of hire or the effective date of contracting
- When there are updates to such Standards of Conduct
- Annually thereafter

Also, you must retain evidence of your distribution of the Standards of Conduct.

You can find these Standard of Conduct requirements in:

- 42 C.F.R. § 422.503(b)(4)(vi)(A) for Medicare Advantage
- 42 C.F.R. § 423.504(b)(4)(vi)(A) for Part D
- Manual, Chapter 9 § 50.1.1

B. Exclusion list screenings

Federal law prohibits Medicare, Medicaid and other federal healthcare programs from paying for items or services provided by a person or entity excluded from participation in these federal programs. Therefore, prior to hire and/or contract and monthly thereafter, each First Tier Entity must check the Office of Inspector General (OIG) and General Services Administration (GSA) “exclusion lists” to confirm that employees and Downstream Entities performing administrative and/or healthcare services for Aetna’s Medicare Plans aren’t excluded from participating in Federally-funded healthcare programs. You can use these websites to perform the required exclusion list screening:

- Office of Inspector General (OIG) List of Excluded Individuals and Entities
- General Services Administration (GSA) System for Award Management (SAM)

Also, FDRs must maintain evidence they checked these exclusion lists. You can use logs or other records to document that you’ve screened each employee and Downstream Entity in accordance with current laws, regulations and CMS requirements.

You must perform exclusion list screenings

You’re not alone. We’re also required to check these exclusion lists prior to the hiring or contracting of any new employee, temporary employee, volunteer, consultant, governing body member, or FDR, and monthly thereafter. We cannot check these exclusion lists for your employees and Downstream Entities. So, to make sure we comply with this CMS requirement, you must confirm that your permanent and temporary employees and Downstream Entities...
that provide administrative and/or healthcare services for our Medicare Plans are not on either of these exclusion lists.

**You must take action if an employee or Downstream Entity is on the list**

If any of your employees or Downstream Entities are on one of these exclusion lists, you must immediately remove them from work directly or indirectly related to Aetna’s Medicare Plans and notify us right away.

These exclusion list requirements are noted in § 1862(e)(1)(B) of the Social Security Act, 42 C.F.R. §§ 422.503(b)(4)(vi)(F), 422.752(a)(8), 423.504(b)(4)(vi)(F), 423.752(a)(6), 1001.1901, and further described in the Manual, Chapter 9 § 50.6.8.

**C. Reporting FWA and compliance concerns to Aetna**

There are a number of ways to report suspected or detected non-compliance or potential FWA. Don’t worry – your reports are confidential. You can find this information in Aetna’s Reporting Mechanism Poster. Just click the link at the end of this guide. You can share the poster with your employees or Downstream Entities. You can also keep it as a reference tool and use your own internal processes for reporting and collecting these issues. If you choose to use your own processes, make sure you report it to Aetna. Refer back to the Code of Conduct section for information on Aetna’s reporting guidelines.

You must adopt and enforce a zero-tolerance policy for retaliation or intimidation against anyone who reports suspected misconduct.

Dedicated to Aetna’s Medicare Compliance Program is John Wells, Medicare Compliance Officer, who is based in Maryland. Questions or concerns for John and/or his Medicare compliance subject matter experts can be sent to the following mailbox: MedicareFDR@aetna.com.

**D. Offshore operations & CMS reporting**

To help make sure we comply with applicable federal and state laws, rules and regulations, you’re prohibited from using any individual or entity (Offshore Entity) to perform services for Aetna’s Medicare Plans if the individual or entity is physically located outside of one of the fifty United States or one of the United States Territories (i.e., American Samoa, Guam, Northern Marianas, Puerto Rico, and Virgin Islands). The only exception to this is if an authorized Aetna representative agrees in advance and in writing to the use of such Offshore Entity.

**Notify us immediately if you plan to use an Offshore Entity**

If you perform services offshore or use an Offshore Entity to perform services involving the receipt, processing, transferring, handling, storing, or accessing of Medicare Member protected health information (PHI) and we approve the arrangement, we must submit an attestation to
CMS. One example provided by CMS of offshore services that trigger this attestation requirement is “offshore subcontractors that receive radiological images for reading, because beneficiary personal health information (PHI) is included with the radiological image and the diagnosis is transmitted back to the U.S.” Therefore, you must immediately notify your Aetna Relationship Manager if you plan to use an Offshore Entity.

**E. Specific federal and state compliance obligations**

Based upon the services that you/your organization performs for Aetna’s Medicare plans, you may be subject to other federal and state laws, rules and regulations that we didn’t describe in this guide. If you have questions about the Medicare compliance requirements for the services that you/your organization perform, consult your Aetna Relationship Manager.

**F. Monitoring and auditing of First Tier and Downstream Entities**

CMS requires that we develop a strategy to monitor and audit our First Tier Entities. This helps ensure compliance with all applicable laws and regulations and that our First Tier Entities monitor the compliance of their Downstream Entities. Therefore, if you choose to subcontract with other individuals/parties to provide administrative and/or healthcare services for Aetna’s Medicare Plans, you must make sure that these Downstream Entities abide by all laws and regulations that apply to you as a First Tier Entity. This includes the Medicare Compliance Program requirements described in this guide.

Also, you/your organization must conduct sufficient oversight to test and ensure that your employees and Downstream Entities are compliant with applicable laws, retain evidence of completion, conduct root cause analysis and implement corrective action plans or take disciplinary actions, as necessary, to prevent recurrence of non-compliance with applicable laws.

**Expect routine monitoring and audits**

We routinely monitor and periodically audit First Tier Entities. This helps us ensure compliant administration of our contracts with CMS to offer Medicare Plans, as well as applicable laws and regulations. Each First Tier Entity must cooperate and participate in these monitoring and auditing activities. If a First Tier Entity performs its own audits, we may request the audit results affecting Aetna’s Medicare business. Also, we expect First Tier Entities to routinely monitor and periodically audit their Downstream Entities.

If we determine that an FDR doesn’t comply with any of the requirements in this guide, we’ll require the FDR to develop and submit a Corrective Action Plan (CAP). We can help the FDR address the identified compliance issues.
These Monitoring and Auditing requirements are noted in 42 C.F.R. § 422.503(b)(4)(vi)(F) for Medicare Advantage and 42 C.F.R. § 423.504(b)(4)(vi)(F) for Part D, and further described in the Manual, Chapter 9 § Section 50.6.6.

Questions/Concerns
For compliance questions or concerns, you can email the Aetna mailbox: MedicareFDR@aetna.com

Toolbox of resources for FDRs
The grid below provides links to helpful tools and resources.

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<th>General compliance and FWA training</th>
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<tr>
<td><strong>Don't have training in place?</strong></td>
<td>No need to develop your own. You can download the CMS General Compliance and FWA training. Also, you can take the training online (after registration) on the Medicare Learning Network.</td>
</tr>
<tr>
<td><strong>Already have your own training in place?</strong></td>
<td>Use this tool to evaluate if your training is equivalent to CMS’.</td>
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<tr>
<td><strong>Proof of training completion</strong></td>
<td>This sample log provides a way to document your employee’s completion of CMS’s General Compliance and Fraud Waste and Abuse Training. You can also modify it to record completion of your own training. Or, you can send this log to your downstream entities to use in monitoring their training completion.</td>
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<tr>
<th>Code of Conduct and compliance policies</th>
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<tr>
<td><strong>Don't have your own code?</strong></td>
<td>If not, feel free to distribute Aetna’s Code of Conduct to your employees.</td>
</tr>
<tr>
<td><strong>Medicare compliance department policies</strong></td>
<td>Our Code of Conduct explains our compliance program, but these policies provide more detail about our Medicare Compliance Program.</td>
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<tr>
<td><strong>Share our Code and policies</strong></td>
<td>Use this announcement template to share Aetna’s Code of Conduct and compliance policies.</td>
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<tr>
<th>Exclusion list screenings</th>
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<tr>
<td><strong>Where is the OIG?</strong></td>
<td>Complete OIG exclusion list screenings prior to hire/contracting and monthly for your employees and downstream entities.</td>
</tr>
<tr>
<td><strong>Where is the GSA/SAM?</strong></td>
<td>Complete GSA exclusion list screenings prior to hire/contracting and monthly for your employees and Downstream Entities.</td>
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<th>Reporting mechanisms</th>
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<tr>
<td><strong>How do I report non-compliance or potential fraud, waste, and abuse (FWA) to Aetna?</strong></td>
<td>This poster provides ways for reporting issues that impact Aetna, directly to Aetna. Feel free to share this throughout your organization so that your employees know how to report concerns. Remember, you must report suspected or detected non-compliance or potential FWA that impact Aetna.</td>
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<td>Monitoring and oversight</td>
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<tr>
<td>Downstream oversight</td>
<td>You must conduct oversight of your Downstream Entities. You can do this by requesting attestations from your Downstream Entities to monitor their compliance. Use this <a href="#">attestation</a> to ensure those you contract with (and touch Aetna’s Medicare business) comply with the Medicare Compliance Program Requirements.</td>
</tr>
<tr>
<td>Check yourself</td>
<td>You can use this <a href="#">example tool</a> to assess your compliance with the Medicare Compliance Program Requirements. Your organization can also modify the tool to assess compliance of your Downstream Entities.</td>
</tr>
<tr>
<td>Other tools</td>
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<tr>
<td>More tools</td>
<td>You can find other <a href="#">resources</a> online. If you have ideas for tools that would assist you in meeting the Medicare Compliance Program Requirements, send an email to <a href="mailto:MedicareFDR@aetna.com">MedicareFDR@aetna.com</a>.</td>
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