

Frequently Asked Questions (FAQs) - Table of Contents

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I. CODE OF CONDUCT, COMPLIANCE, FWA AND HIPAA TRAININGS

1. What are the Compliance Program Training Requirements?

Compliance and FWA Training: CMS requires Medicare Advantage Organizations (MAO) and Qualified Health Plans (QHP) in the Federally-Facilitated Marketplaces (FFM) to ensure that general compliance and fraud, waste, and abuse training is communicated to their First Tier, Downstream, and Related Entities (FDRs) who have involvement in the administration or delivery of federally governed health care programs. The CMS compliance program training is

designed to ensure: (1) FDRs have at least a basic knowledge and understanding of compliance program requirements; and (2) FDRs are knowledgeable about compliance and FWA issues and how to appropriately address them.

HIPAA Training: The HIPAA Privacy Rule requires training to all of health plans workforce, as necessary and appropriate to their functions. Employees who handle PHI must be made aware of revised standards as they are implemented and understand the new policies.

Code of Conduct: Piedmont's Code of Conduct communicates to employees and FDRs that compliance is everyone's responsibility. It describes Piedmont's expectations that all employees conduct themselves in an ethical manner; that issues of noncompliance and potential FWA are reported through appropriate mechanisms; and that reported issues will be addressed and corrected. In order to be effective, the Code must be distributed to employees who support Piedmont's Medicare business.

2. Important Definitions - What are the definitions of the various types of entities and how do I know which one applies to my organization?

Covered Entity – Health plan, health care clearinghouse, or health care provider who transmits health information in electronic form in connection with one or more transactions. Piedmont is considered a covered entity.

Medicare Advantage Organization – A private insurance company that contracts with Medicare and combines all Part A (hospitalization) and Part B (doctor's visit coverage) benefits into one health plan while providing the same medically-necessary services as Original Medicare. Some, but not all, may offer Part D (Prescription Drug Coverage) at no additional cost. Piedmont is considered a Medicare Advantage Organization with Part D Coverage.

Qualified Health Plan – Under the Affordable Care Act, an insurance plan that is certified by the Health Insurance Marketplace, provides essential health benefits, follows established limits on cost-sharing, and meets other requirements. Piedmont is considered a Qualified Health Plan.

Delegated Entity (aka First Tier Entity) – any party that enters into a written arrangement, acceptable to CMS, with a Medicare Advantage Organization (MAO) or Federally-Facilitated Marketplace (FFM) plan sponsor or applicant to provide administrative services or health care services to individuals under the Medicare Advantage program or Marketplace program. If your

organization has a contract directly with Piedmont to support our Medicare Advantage or Marketplace product, your organization is considered a Delegated or First Tier Entity.

Downstream Entity – any party that enters into a written agreement, acceptable to CMS, with persons or entities involved with the Medicare Advantage or Marketplace benefit, below the level of first tier entity. These arrangements continue down to the level of the ultimate provider of both health and administrative services. Downstream entities do not have a direct contract

with Piedmont, but may be contracted with a Delegated or First Tier Entity to perform work on one of Piedmont's plans on the Delegated or First Tier Entity's behalf.

Related Entity – any entity that is related to an MAO or FFM Sponsor by common ownership or control and performs some of the sponsor's management functions under contract or delegation; furnishes services to enrollees under an oral or written agreement, or leases real property or sells materials to the MAO or FFM plan sponsor at a cost of more than \$2500 during a contract period.

FDRs – collective term for First Tier, Downstream or Related Entities.

Business Associate – any person or business who performs certain functions on Piedmont's behalf that involves the use or disclosure of protected health information (PHI). Piedmont must have a valid Business Associate Agreement (BAA) with them that assures they will appropriately safeguard any PHI they create or receive on Piedmont's behalf. All BAAs have to be updated to comply with the new Omnibus Rule. If your organization uses or discloses any PHI on Piedmont's behalf, your organization is considered a Business Associate.

Workforce Member – employees, faculty, medical staff, residents, fellows, students, volunteers, trainees, vendors, contractors, consultants, agents and other persons whose conduct, in the performance of work for a covered entity, is under the covered entity's direct control, whether or not they are paid by that covered entity. This includes any individual from your organization or any of your FDRs that perform functions on behalf of Piedmont.

3. Who must complete these trainings?

Because of your contractual relationship with Piedmont, you are considered an FDR; therefore, CMS requires that your organization complete the training.

While FDRs are required to comply with the compliance program training requirements, CMS does not expect an FDR's entire staff would necessarily be subject to the requirement. Below are examples of the critical roles within an FDR that are clearly required to fulfill the training requirements.

- Senior administrators or managers directly responsible for the FDR's contract with Piedmont (e.g. Senior Vice President, Departmental Managers, Chief Medical or Pharmacy Officer)
- Individuals directly involved with establishing and administering Piedmont's formulary and/or medical benefits coverage

- Individuals involved with decision-making authority on behalf of Piedmont (e.g. clinical decisions, coverage determinations, appeals and grievances, enrollment/disenrollment functions, processing of pharmacy or medical claims)
- Reviews of beneficiary claims and services submitted for payment
- Individuals with job functions that place the FDR in a position to commit significant noncompliance with CMS program requirements or healthcare fraud, waste and abuse.

It is your responsibility to identify those parties that serve in this capacity for you and to ensure they complete the training. When in doubt about a particular position, we encourage you to require the training. Piedmont will be happy to work with you to assess which positions must complete the training.

4. When should this training be completed?

The training must be completed within 90 days of your and your employee's initial hire (contract) date and at least annually thereafter. Your Downstream and Related Entities must also be trained within this time frame.

5. How often does the training have to be taken?

The training must be completed initially upon hire/contracting and annually thereafter.

6. Does an FDR have to use the CMS MLN training or can they use a different version of training?

CMS created the FWA and General Compliance Training Modules on the MLN in order to simplify compliance training and ensure that duplication of effort is avoided for FDRs that hold contracts with multiple Part C and Part D contracting organizations. You may have already completed this for another plan in which case you need not do it again.

As of 2/1/17, CMS has 3 options for completing the training.

- 1) FDRs can complete the general compliance and/or FWA training modules located on the CMS MLN. Once an individual completes the training, the system will generate a certificate of completion. The MLN certificate of completion must be accepted by all government regulated health plan sponsors.
- 2) FDRs can incorporate the content of the CMS standardized training modules from the CMS website into their organizations' existing compliance training materials/systems.
- 3) FDRs can incorporate the content of the CMS training modules into written documents for providers (e.g. Provider Guides, Participation Manuals, Business Associate Agreements, etc.).

Piedmont's web portal directs you to the CMS MLN trainings. We do not have any other version of the training available. Should your organization choose to create your own trainings as allowed in Option 2 or 3, please note CMS requires the training to include all content in the CMS standardized training modules. CMS will allow modifications to the appearance of the content (i.e. font, color, background, format), but the training content cannot be modified. You do have the option to enhance or wrap around the CMS training content by adding topics specific to your organization or an employee's job function.

7. Can an FDR use its own HIPAA Training?

Yes, if it is equivalent to Piedmont's HIPAA Training.

8. Can an FDR use its own Code of Conduct?

Yes, if it is equivalent to Piedmont's Code of Conduct.

9. What kind of documentation is needed to show the training has been completed?

Evidence may be in the form of employee attestations, employee attendance/training logs, or other means determined by you to best represent fulfillment of your obligations. You should retain evidence of completion for at least 10 years. Piedmont and/or CMS may request this evidence to ensure completion of these requirements.

10. What documentation does Piedmont need after completion of this training?

Piedmont collects an Attestation to confirm completion of the training requirements. You can access a copy of this Attestation on the “Instructions and Requirements” page.

11. What will happen if I don’t complete the required training?

If areas of non-compliance are determined, enforcement actions may be taken to both cure the deficiencies and prevent future occurrences. Enforcement actions, such as corrective action plans and/or contract termination, may vary depending upon the severity of the issue. CMS requirements dictate this training, so completion of it is not an option. As a Piedmont First Tier Entity, you are expected to enforce completion of these requirements with your Downstream and Related Entities as well.

12. Who do I contact if I have more questions about this training?

If you have any questions about the notices you’ve received about training needs, you should contact Garland Morton, Compliance Manager at 434-947-4463 x 306 or by email to gmorton@pchp.net.

II. SANCTION, DEBARMENT, EXCLUSION LIST

13. What is the OIG exclusion list?

OIG’s (Office of Inspector General’s) List of Excluded Individuals/Entities (LEIE) provides information to the health care industry, patients and the public regarding individuals and entities currently excluded from participation in Medicare and other Federal health care programs. The effect of an exclusion is that no payment will be made by any federal health care program for any items or services furnished, ordered or prescribed by an excluded individual or entity. Sponsors shall not use federal funds to pay for services, equipment or drugs prescribed or provided by a provider, supplier, employee or FDR excluded by the OIG. This payment prohibition applies to the excluded person, anyone who employs or contracts with the excluded person, any hospital or other provider for which the excluded person provides services, and anyone else. The exclusion applies regardless of who submits the claims and applies to all administrative and management services furnished by the excluded person. CMS prohibits payments by Piedmont directly or indirectly to anyone on this list.

14. What is the SAM exclusion list?

The SAM dataset contains a daily snapshot of active exclusion records entered by the U.S. Federal government identifying those parties excluded from receiving Federal contracts, certain subcontracts, and certain types of Federal financial and non-financial assistance and benefits. The data was formerly contained in the Excluded Parties List System (EPLS). In addition to health care providers, the GSA SAM also includes non-health care contractors. This electronic,

web-based system keeps its user community aware of administrative and statutory exclusions across the entire government, and individuals barred from entering the U.S.

15. What are my requirements related to Federal health care program exclusion and debarment checks?

FDRs must review the OIG and SAM at the time of hire/contracting and monthly thereafter for their current employees/contractors, health care professionals, Delegated or Related Entities that work on Medicare Advantage or Marketplace programs to ensure that none are excluded from participating in Federal health care programs. For more information or access to the OIG LEIE database, go to www.oig.hhs.gov/exclusions/index/asp. For more information or access to the GSA SAM database, go to www.sam.gov.

16. How often do the exclusion/debarment checks have to be completed?

The checks must be completed initially before hire/contracting and then monthly thereafter. This frequency is determined by CMS.

17. What evidence should I submit to show that these checks are completed?

The documentation or evidence may vary depending on the system used to complete these checks. If you perform a manual search of the website lists, you may use a screen print of the result of the check. If you perform these checks using a more automated system or program, your documentation may be based on the information available within that system. Regardless of the process you use to perform these required checks, the documentation to evidence compliance with this requirement should clearly identify the name of the entity/individual checked, the date the check was performed, and the results of the check.

18. What if an individual or entity is identified on one of the exclusion/debarment lists?

If you identify an excluded individual or entity employed or contracted by your organization, you must report this to Piedmont. This entity must be immediately removed from directly or indirectly servicing Piedmont Medicare or Marketplace products.

III. VALIDATION/AUDIT OF EFFECTIVE COMPLIANCE PROGRAM REQUIREMENTS

19. What documentation/evidence will CMS and/or Piedmont ask FDRs for to support their compliance with Piedmont's Compliance Program?

A variety of evidence could be requested by CMS and/or Piedmont from FDRs such as those that can be found on Attachment A: Evidence Examples.

20. Why is Piedmont asking for all of this information?

CMS requires that Piedmont conduct oversight of contracted entities to ensure that they are meeting CMS compliance expectations for all Part C & D and Marketplace related responsibilities. You are required to provide documentation at the request of Piedmont or CMS as depicted within your contractual agreement. Please note that CMS requires your evidence of training completion to be at the level of your employees (e.g., employee attendance/training logs, sign-in sheets, employee attestations or certifications, etc.).

21. Why is Piedmont asking about how long I retain my employee training and disciplinary records?

CMS requires that records are retained for at least ten years and requires that we validate your compliance.

22. Why is Piedmont asking about my subcontractors (downstream) contractual arrangements?

CMS requires that Piedmont assess your oversight of your downstream contractual arrangements that are used by you to service Piedmont's Medicare and Marketplace products. This assessment is required to ensure that you have a process to validate their compliance and impose corrective actions when deficiencies are identified which may include termination of your contract with the entity if the deficiencies cannot be corrected and hence warrant such action.

23. What oversight is expected for my subcontractors?

CMS requires that you, your organization, and any of your Downstream and Related Entities maintain compliance of all CMS requirements, as applicable, while servicing Piedmont's Medicare and Marketplace products. This includes the requirements already mentioned, as well as any others that may apply that are not listed in these FAQs. For example, CMS requires the reporting and oversight of any and all entities that manage Protected Health Information (PHI) offshore. Therefore, it is expected that you identify any such services for your own organization or any of your Downstream/Related Entities in order to conduct oversight of those processes and report them to Piedmont. If you use Downstream and/or Related Entities for Piedmont Medicare and Marketplace products, you must ensure that proper oversight is conducted comprehensively for all CMS requirements through ongoing monitoring processes and annual audits.

24. What monitoring and audit protocols are required of me?

You are required to monitor and/or audit all of your FDRs who serve in any function relating to the Medicare or Marketplace programs. Should any audit results find that an FDR has been non-compliant with a Medicare/Marketplace requirement, you should notify Piedmont immediately. Additionally, your organization should be readily available for an audit (or desk audit) by Piedmont's compliance department at any time after contracting with Piedmont. This allows Piedmont to assess and review its compliance program readiness and effectiveness, which includes oversight of its FDRs.

EVIDENCE EXAMPLES

Summary of Expectation	Examples of Evidence/Documentation that may be Requested
FDR employees and Downstream/Related Entities <u>received</u> Piedmont's or equivalent Code of Conduct (Code) upon hire/initial contracting and annually thereafter	<ul style="list-style-type: none"> • Policy • Organization attestation confirming dissemination to employees and Downstream/Related Entities • Employee attestations confirming receipt • Participation/onboarding/orientation manuals • Downstream/Related Entity contractual provision
FDR employees and Downstream/Related Entities <u>completed</u> the CMS MLN or equivalent FWA and General Compliance Training upon hire/initial contracting and annually thereafter	<ul style="list-style-type: none"> • Policy • CMS MLN Certificate of Completion • Organization attestation confirming dissemination to employees and Downstream/Related Entities • Employee attestations confirming receipt • Training agendas and sign-in sheets for FWA and Compliance training • Downstream/Related Entity contractual provision
FDRs check OIG & SAM lists for employees and Downstream/Related Entities prior to hire/contracting and monthly thereafter	<ul style="list-style-type: none"> • Policy • Website screenshots of list checks • Automated results from acquired tools (V-Lookup) • Attestation from individuals within organization that conducts these ongoing checks (e.g. Human Resources, etc.) • Evidence of reporting excluded individuals/entities to Piedmont as they are identified • Downstream/Related Entity contractual provision
FDR employees and Downstream/Related Entities <u>received</u> reporting mechanisms for reporting potential or actual non-compliance and/or FWA either internally, then to Piedmont, or to Piedmont directly (including non-retaliation policy for good faith reporting)	<ul style="list-style-type: none"> • Policy • Reporting Mechanism Posters in facilities • Downstream/Related Entity contractual provision • Organization attestation confirming dissemination
FDR retains records related to Piedmont's Medicare and Marketplace Product service delivery/activities for a period of no less than 10 years	<ul style="list-style-type: none"> • Policy • Record Destruction Schedule • Notice and/or training content disseminated to employees and Downstream/Related Entities • Downstream/Related Entity contractual provision • Organization attestation confirming retention

<p>FDRs conduct sufficient oversight of their Downstream and Related Entities for CMS compliance</p>	<ul style="list-style-type: none"> • Policy • Audit Plan • Audit Reports with review results • Monitoring of entity functions with results • Any corrective/preventive action plans for identified deficiencies • Reporting of deficiencies to authoritative bodies including Piedmont, as necessary • Organization attestation confirming oversight completion and downstream compliance
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NOTE: This table is intended to be a list of examples only. The expectations listed are not intended to be all inclusive of CMS compliance requirements. Further, the examples of evidence listed are not intended to be a list of all items required to be in place nor a declaration of the maximum evidence needed to demonstrate compliance.