



FDR Guide to Medicare Compliance

First Tier,
Downstream and
Related Entities
(FDR) Devoted
Health's Medicare
Compliance
Program Guide



Introduction to Devoted Health's Compliance Program

Our Medicare Compliance and Fraud Waste and Abuse (FWA) program helps us serve our members ethically and ensures that we remain compliant with Federal regulations as well as protecting the Medicare Trust Fund. Our plan is designed to:

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

CMS requires that Devoted Health fulfill specific Medicare compliance program requirements. The Code of Federal Regulations (CFR) outlines these requirements, and they are defined by CMS in the January 11, 2013, Compliance Program Guidelines in Chapter 21 of the Medicare Managed Care Manual and Chapter 9 of the Prescription Drug Benefit Manual.





What are First Tier, Downstream and Related Entities (FDRs)?

First Tier Entity is any party that enters into a written arrangement, acceptable to CMS, with an MA organization or Part D plan sponsor or applicant to provide administrative services or health care services to a Medicare-eligible individual under the MA program or Part D program. (See 42 CFR §§ 422.500 and 423.501.)

Downstream Entity is any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the MA benefit or Part D benefit, below the level of the arrangement between an MA 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 CFR §§ 422.500 and 423.501.)

Related Entity means any entity that is related to an MA organization or Part D sponsor by common ownership or control and: 1. Performs some of the MA organization or Part D plan sponsor's management functions under contract or delegation 2. Furnishes services to Medicare enrollees under an oral or written agreement 3. Leases real property or sells materials to the MA organization or Part D plan sponsor at a cost of more than \$2,500 during a contract period (See 42 CFR §§ 422.500 and 423.501.)

FDRs Providing Administrative Services

The Medicare compliance program requirements apply to entities with which we contract to perform administrative service functions relating to our MAPD contract with CMS. Some examples of administrative service functions include:

- Claims processing
- Utilization Management
- Sales
- Pharmacy Benefits
- Correspondence



FDR Medicare compliance program and attestation requirements

Compliance program requirements

Your organization and all of your Downstream Entities must comply with Medicare compliance program requirements. This guide summarizes the Medicare compliance program requirements. 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:

- Completion of the CMS Combating Medicare Parts C and D Fraud, Waste, and Abuse Trainings located in the CMS MLN
- Medicare Parts C and D General Compliance Training located in the CMS MLN
- Code of conduct/compliance program policy distribution
- Exclusion list screenings
- Reporting FWA and compliance concerns to Devoted
- Offshore operations and CMS reporting

Attestation requirements

As an FDR providing services on behalf of Devoted Health, you must maintain evidence of your compliance with these Medicare compliance program requirements (for example, CMS certificates of FWA training completion) 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 health care and/or administrative services for Devoted Health's Medicare plans. This could be your Compliance Officer, Chief Medical Officer, practice manager/administrator, an executive officer or similar positions.



General Compliance and Fraud, Waste and Abuse (FWA) training

Overview:

Beginning January 1, 2019, CMS no longer requires Plan Sponsors to ensure that their FDRs complete CMS-published training modules. CMS's stated goal is to reduce administrative burden and to provide each Plan Sponsor with flexibility to oversee FDR compliance as it sees fit.

FDRs must be able to demonstrate that their employees have fulfilled these training requirements. Examples of proof of training include:

- Copies of sign-in sheets
- Employee attestations
- Electronic certifications from the employees taking and completing the training

Who should complete training?

Not every employee needs to take training. Below are examples of critical roles within an FDR that clearly should be required to fulfill the training requirements:

- Senior administrators or managers directly responsible for the FDR's contract with Devoted (for example, senior vice president, departmental managers, chief medical or pharmacy officer)
- Individuals directly involved with establishing and administering Devoted's formulary and/or medical benefits coverage policies and procedures
- Individuals involved with decision-making authority on behalf of Devoted (for example, clinical decisions, coverage determinations, appeals and grievances, enrollment/disenrollment functions, processing of pharmacy or medical claims)
- Reviewers 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



General Compliance and Fraud, Waste and Abuse (FWA) training (cont'd)

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 during each calendar year (January 1 – December 31) thereafter

Not sure which employees at your organization should take the training?

Reach out to Devoted's Medicare Compliance Officer with any questions regarding required trainings.

**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 Part A or B of the Medicare program or through accreditation as a supplier of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). You can find the training requirements and information about deemed status in:

- 42 CFR § 422.503(b)(4)(vi)(C) for MA
- 42 CFR § 423.504(b)(4)(vi)(C) for Part D
- Manual, Chapter 21 § 50.3

Code of Conduct & Compliance Program Policy Distribution

What is your Organization's Code of Conduct?

In order for your employees to perform business functions on behalf of Devoted Health, they must follow Devoted's Code of Conduct or your own comparable Code of Conduct. Your employees should also have access to Devoted Health's Medicare Compliance Policies if they are not incorporated into your Code of Conduct. Devoted Health's Code of Conduct and our Compliance Policies can be accessed at our website: www.Devoted.com under our Policies section.

The written Standards of Conduct and Compliance Policies must contain all of the elements set forth in Section 50.1 and its subsections of Manual, Chapter 21, and articulate the entity's commitment to comply with federal and state laws, ethical behavior and compliance program operations. You must distribute standards of conduct/policies:

- Within 90 days of hire or the effective date of contracting
- When there are updates to the standards of conduct
- Annually thereafter (you must retain evidence of your distribution of the standards of conduct)

You can find the standards of conduct requirements in:

- 42 CFR § 422.503(b)(4)(vi)(A) for MA
- 42 CFR § 423.504(b)(4)(vi)(A) for Part D
- Medicare Managed Care Manual, Chapter 21 § 50.1

Exclusion Screenings

Screening your Employees, Temporary Employees, Contractors, and Downstream Entities

Federal law prohibits payment for items or services furnished or prescribed by an excluded provider or entity. Therefore, before hiring or contracting, and monthly thereafter, each FDR must check exclusion lists from the Office of Inspector General (OIG) List of Excluded Individuals/Entities (LEIE), the U.S. General Services Administration (GSA) System for Award Management (SAM), the CMS Preclusion List, and all available State Exclusion Lists (reminder: if an individual or entity is excluded in one state, they are excluded in all states). This is to confirm that employees and Downstream Entities performing administrative and/or health care services for Devoted Health aren't excluded or precluded from participating in federally funded healthcare programs.

FDRs must maintain evidence they checked these exclusion or preclusion 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. Be sure to retain evidence of the screening that was conducted including date of occurrence, the results of the screening and any actions taken if sanctioned individuals or entities were identified.

You must take action if an employee or Downstream Entity is on the exclusion or preclusion list. If any of your employees or Downstream Entities are on one of these exclusion or preclusion lists, you must immediately remove them from work directly or indirectly related to Devoted's plans and notify us right away.

These exclusion list requirements are noted in §§ 1128, 1156, 1862(e)(1)(B), and 1903(i)(2) 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; 42 U.S.C. § 1396a(a)(39); and as further described in the Medicare Managed Care Manual Chapter 21 § 50.6.8, Letter from CMS to State Medicaid Directors 5 (Jan. 16, 2009), and Letter from CMS, CPI-CMS Informational Bulletin, Affordable Care Act Program Integrity Provisions – Guidance to States — Section 6501 – Termination of Provider Participation under Medicaid if Terminated under Medicare or other State Plan (Jan. 20, 2012).

Offshore Approval Requests

Devoted is required to notify Government Entities of our FDRs' use of offshore resources to perform delegated functions. This requirement applies to both your organization's employees tasked to directly perform the delegated functions, and to downstream entities you have engaged to perform delegated functions ("subcontractors") on your behalf.

If you intend to directly perform delegated functions offshore and/or subcontract delegated functions offshore, you must first submit the [Offshore Approval Request Form](#) and receive approval from us **before** moving any functions offshore.

- You may find the form link [here](#), and on our website <https://www.devoted.com/compliance/compliance-fdrs/>.

Offshore functions are required to be reported annually on the FDR Attestation Form. If any changes in Offshore performance and/or subcontracting occur, please submit a new form via this [link](#).

- For Offshore Questions, please email us at: compliance@devoted.com and offshoreprogram@devoted.com.

Devoted's FDR Auditing, Oversight, and Monitoring Program

FDR Audits

- Pre-Delegation Audits
- Annual Audits
- Ad hoc Audits

FDR Oversight & Monitoring

- Compliance Program
- Routine monitoring
- Identifying & responding to Compliance Risks

FDR Attestations

- FDR Attestation
- FDR Readiness Attestation

Devoted conducts audits on a pre-delegation, annual, and ad hoc basis.

- Devoted conducts Pre-Delegation FDR Audits prior to the initiation of a net-new agreement with a new FDR or a new statement of work with an existing FDR, and are to be completed prior to the agreement effective date.
- Devoted conducts Annual FDR Audits as part of our Annual FDR Audit Workplan. During the Workplan development, Devoted Compliance conducts a Risk Assessment, which includes the functions delegated of the FDRs and the performance of the FDRs, while considering existing risk-enhancing and risk-mitigating factors in place. An Annual FDR Audit may range in scope from an end-to-end delegation audit to a focused audit (e.g., an element of the Delegation, Compliance Oversight, etc.)
- Devoted may conduct Ad hoc FDR Audits that were not selected as part of our Annual FDR Audit Workplan.
- All audits are expected to be completed by Devoted within 90 days.
- Devoted is regularly audited by external bodies, such as by CMS (annual & ad hoc) and AAAHC (triennial). As applicable, Devoted will require information from our FDRs to respond to the audit.
- Devoted Compliance may also issue a Corrective Action Plan to ensure identified issues of non-compliance are fully remediated.

FDR Oversight & Monitoring

Devoted and FDRs are expected to conduct Oversight & Monitoring Activities on an ongoing basis.

- At Devoted, Compliance monitors Business Area Reporting to ensure oversight activities are completed, reported timely, and compliant. Devoted's Compliance oversight includes monitoring of all internal, external (FDR), and FWA auditing, monitoring, and investigation activities. Activities are generally reported on a regular established cadence to Compliance by the Business/FDR.
- Oversight and monitoring is specific to each Business Area and FDR to ensure adherence to all CMS and contractual requirements. Each Business Owner implements an Oversight and Monitoring Standard Operating Procedure specific to the Business or FDR. As applicable, this process can include dashboard, reporting, QA of letters, calls, universe, and meeting oversight and monitoring.
- Devoted Compliance works in partnership with the Business/FDR to resolve any findings as a result of auditing, monitoring, and/or investigation activities. Devoted Compliance hosts regular meetings with the Business, during which reporting is reviewed. Devoted Compliance may issue ad-hoc monitoring and/or auditing of processes based on findings reported by the Business. Devoted Compliance may also issue a Corrective Action Plan to ensure identified issues of non-compliance are fully remediated.

FDR Attestations

Devoted and FDRs are expected to provide certain Attestations.

- CMS requires Devoted and all FDRs comply with certain requirements. Devoted collects the [FDR Attestation](#) from all existing FDRs on an annual basis, and all new FDRs as part of our pre-delegation audit, as part of providing evidence of compliance.
 - Devoted engages its annual FDR Attestation Process in Q2 to ensure all FDR Attestations are collected prior to Annual Enrollment Period (AEP).
- CMS also requires Devoted provide an annual Readiness Checklist to CMS that affirms Devoted and all FDRs are ready to implement the next year's contract with CMS. Devoted collects the FDR Readiness Attestation ([example: CY 2025 FDR Readiness Attestation](#)) as part of completing our Readiness Checklist for CMS.
 - CMS issues the Readiness Checklist to all Medicare Advantage Plans in October each year.
 - Devoted will collect the FDR Readiness Attestation in Q4 on an annual basis.
- Failure to complete the required Attestations will result in corrective action, up to and including termination of the contract.

Compliance @ Devoted

*Don't Hesitate to Report Potential
Non-Compliance & FWA Issues*

At Devoted we want to hear any potential violations. Every employee has an obligation to report any concerns about a potential breach in the Code of Conduct, compliance concern and/or potential Fraud, Waste, and Abuse (FWA) without fear of retaliation. We are a company built on openness and trust.

There are several ways to report your concerns:

- Call our hotline (855) 292-7485 (*You can remain anonymous*)
- Report to the Devoted Medicare Compliance Website
- Report to your organization's Human Resources
- Report to your manager



Shannon O'Kane
CHIEF COMPLIANCE OFFICER



**Explore the Compliance
Department here at Devoted
Health:**

Compliance Website:

<https://www.devoted.com/compliance>

Questions/Concerns?

If you have any questions regarding this document, concerns about what and who to report information to regarding what is required in this document, please reach out to Devoted Health's Compliance Website: <https://www.devoted.com/compliance>
Compliance Hotline - 855-292-7485





INFO@DEVOTED.COM
(617) 958-1611 221

CRESCENT STREET, SUITE 202
WALTHAM, MA 02453