

Welcome to Navitus Health Solutions!

What It Means to be a First Tier, Downstream or Related Entity

As a contracted Navitus pharmacy providing services to Medicare and Medicaid members, it is important to know that you qualify as a First Tier, Downstream or Related Entity (FDR). Navitus participating pharmacies are FDRs and as such must have strong practices related to compliance and prevention and detection of fraud, waste, and abuse. FDRs must also engage in training, exclusion checks, policies, records management, and reporting of issues.

Navitus understands that these requirements may be new to you or you have not recently reviewed them. Navitus receives many questions from FDRs on meeting these requirements which are outlined below.

FREQUENTLY ASKED QUESTIONS ON COMPLIANCE AND FWA REQUIREMENTS

1. What does CMS mean by an FDR?

CMS defines First Tier, Downstream and Related entities (FDR) as follows:

First Tier Entity - any party that enters into a written arrangement, acceptable to CMS, with a Medicare Advantage Organization (MAO) or Part D plan sponsor or applicant to provide administrative services or health care services to a Medicare-eligible individual under the Medicare Advantage program or Part D program. Navitus Health Solutions (Navitus) is a 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 Part D 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. This includes pharmacies participating in Navitus pharmacy network and vendors providing services to Navitus.

2. What are the Code of Conduct requirements?

FDRs contracted with Navitus must provide either their own or the Navitus Vendor Code of Conduct to their employees (including temporary workers and volunteers), the CEO, senior administrators or managers, governing body members, and subcontractors who are involved in the administration or delivery of Medicare Part D benefits or services within 90 days of hire and annually thereafter, by Dec. 31 of each year. The Navitus Vendor Code of Conduct is accessible on the [Navitus website](#) under the FDR webpage.

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

Yes, however, it must include the required elements found in the Chapter 9 and/or Chapter 21 of the Medicare Managed Care Manual (see links in Question 4).

4. What elements must be included in FWA and general compliance training?

For the list of required training elements, please see the links to Chapter 9 and/or Chapter 21 of the Medicare Managed Care Manual.

- <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf>
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5. Can an FDR use its own Code of Conduct?

Yes, however, it must include the required elements found in the Chapter 9 and/or Chapter 21 of the Medicare Managed Care Manual (see links in Question 3).

6. What if we offer our own training or have completed another plan's training?

If your organization has completed a general compliance and FWA training program through another health plan sponsor, we accept documentation of that training as long as it includes all CMS-required elements. Vendors may not create their own FWA training per CMS requirements.

The CMS Standardized General Compliance and FWA Training Module is accessible at <http://www.cms.gov/MLNProducts>.

7. What kind of documentation is needed to show training was 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 ten years. Navitus and/or CMS may request this evidence to ensure completion of these requirements. See Question 10 for further details.

8. What are my requirements related to Federal health care program exclusion checks?

FDRs contracted with Navitus to provide Medicare Part D services must review the federal exclusion lists, OIG List of Excluded Individuals and Entities (LEIE list) and GSA Systems for Award Management (SAM) prior to hiring or contracting with employees (including temporary workers and volunteers), the CEO, senior administrators or managers, governing body members, and subcontractors who have involvement in the administration or delivery of Medicare Part D benefits or services to ensure that none of these persons or entities are excluded from participation in federal programs. FDRs must continue to review the federal exclusion lists on a monthly basis thereafter. FDRs contracted to provide services to Navitus may be subject to state-based exclusion lists as well. If you identify an excluded party, report this to Navitus immediately.

These exclusion lists can be found at:

<https://oig.hhs.gov/exclusions/> <https://www.sam.gov/>

9. How often do I have to complete these exclusion checks?

CMS guidance requires that exclusion checks be completed prior to hiring/contracting then monthly thereafter.

10. What if I work with other entities that do not contract directly with Navitus?

This did not eliminate the need for completion of training overall or exempt any provider type. This only eliminated use of the CMS MedLearn training as the mandated standard for accomplishing this education.

The CMS Medicare Managed Care and Prescription Drug Manuals on the CMS website under Ch 50.3 still mandate the need for effective training on an annual basis. This is a component of the Navitus FDR Addendum for the participating pharmacy contract.

For pharmacies, NCPDP took this into consideration with the attestation by providing the option "or they may use a non-CMS program that meets all applicable CMS and Federal requirements."

If your organization has contracted with other entities to provide Medicare Part D services on behalf of Navitus, you will need to provide the relevant training materials to that entity and ensure records are kept by the entities that document that they have distributed the Vendor Code of Conduct; have completed FWA and general compliance training; and have conducted HHS/OIG, GSA and state (if applicable) exclusion checks requirements.

11. What kind of documentation do I need to show that the CMS requirements for distribution of standards of conduct, compliance and FWA training, screening of excluded individuals, offshore vendors services, compliance with Medicare law and record retention have been met?

SUMMARY OF EXPECTATION	EXAMPLES OF EVIDENCE/DOCUMENTATION THAT MAY BE REQUESTED
<p>FDR employees and Downstream/Related Entities received Navitus' or equivalent Code of Conduct (COC) upon hire/initial contracting and annually thereafter</p>	<ul style="list-style-type: none"> • Policy • Employee attestations confirming receipt • Training agendas and sign-in sheets for COC training • Participation/onboarding/orientation manuals • Subcontractor contractual provision
<p>FDR employees and Downstream/Related Entities completed Navitus' or equivalent FWA Training upon hire/initial contracting and annually thereafter</p>	<ul style="list-style-type: none"> • Policy • Employee attestations confirming participation • Training agendas, materials and sign-in sheets for FWA training • Proof of deemed status • Subcontractor contractual provision
<p>FDRs check OIG and SAM Lists for employees and Downstream/Related Entities prior to hire/contracting and monthly thereafter</p>	<ul style="list-style-type: none"> • Policy • Website screenshots of list checks • Automated results from acquired tools • Evidence of reporting found individuals/entities to Navitus as they are identified • Subcontractor contractual provision
<p>FDR employees and Downstream/Related Entities received reporting mechanisms for reporting potential or actual non-compliance and/or FWA either internally then to Navitus or to Navitus directly (including non-retaliation policy for good faith reporting)</p>	<ul style="list-style-type: none"> • Policy • Reporting mechanism posters in facilities • Code of Conduct content in trainings with training sign-in sheets, materials, etc. that include reporting and non-retaliation statements • Subcontractor contractual provision
<p>Offshore subcontractors not utilized by FDR to provide Medicare Part D services</p>	<ul style="list-style-type: none"> • Policy • Subcontractor contractual provision

FDR complies with all applicable Medicare laws, regulations and CMS guidance

- Policy
- Subcontractor contractual provision

FDR retains records related to Navitus Medicare product service delivery/activities for a period of no less than 10 years

- Policy
- Record Destruction Schedule
- Notice and/or training content disseminated to employees and Downstream/Related Entities
- Downstream/Related Entity contractual provision

FDRs conduct sufficient oversight of their Downstream and Related Entities CMS compliance

- Policy
- Audit Plan
- Audit Reports with review results
- Monitoring of entity functions with results

12. How do I report suspected non-compliance or fraud, waste or abuse?

You can report by one of these mechanisms:

- Confidential Compliance / FWA Hotline at 855-673-6503
- Confidential FWA email sent to FDR@navitus.com
- Contacting the Navitus Chief Compliance Officer at 608-298-5763

13. Didn't CMS discontinue the requirement to complete CMS-issued general compliance and fraud, waste, and abuse training in 2019?

This did not eliminate the need for completion of training overall or exempt any provider type. This only eliminated use of the CMS MedLearn training as the mandated standard for accomplishing this education.

The CMS Medicare Managed Care and Prescription Drug Manuals on the CMS website under Ch 50.3 still mandate the need for effective training on an annual basis. This is a component of the Navitus FDR Addendum for the participating pharmacy contract.

For pharmacies, NCPDP took this into consideration with the attestation by providing the option "or they may use a non-CMS program that meets all applicable CMS and Federal requirements."