



Vendor/FDR Education

For Suppliers and First Tier, Downstream and Related Entities



Who are our Vendors?

Suppliers are those organizations who are providing our corporate entities with goods and services for us to provide specialty pharmacy or pharmacy benefit services

First Tier, Downstream, or Related Entities (FDRs) are those organizations who are delegated by one of our corporate entities to provide healthcare or administrative services directly to individuals who are covered by Medicare or Medicaid programs.

Business Associates are those organizations who are handling, managing, or disclosing protected health information (PHI) on behalf of one of our corporate entities to support members and patients.



Vendor Expectations

Navitus Health Solutions, Lumicera Health Services, EpiphanyRx and our affiliated corporate entities (collectively “Navitus”) are committed to compliance with all applicable laws, regulations and standards including Medicare and Medicaid programs.

Many of these laws, regulations and standards state that vendors and contractors, to whom we delegate or contract for services, must follow the same laws, regulations and standards as Navitus, as long as those services are provided to or on behalf of Navitus corporate entities.

We want you to understand our Navitus’ compliance requirements for vendors. This is consistent with our Compliance Program which follows guidance from the HHS OIG, CMS, DOJ, and US Sentencing Guidelines.

Key Compliance Requirements

- Follow standards of conduct or equivalent guidelines.
 - If you do not have one, use our [Vendor Code of Conduct](#).
- Train your employees and subcontractors in compliance and fraud, waste, and abuse that meets the effective training requirements of CMS.
 - If you do not have equivalent training, you can use the following resources as a guide.
 - CMS MLN Web-Based Training – Medicare Part C and D Fraud, Waste, and Abuse
 - <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/WebBasedTraining>
 - CMS MLN Web-Based Training – Medicare Part C and D General Compliance Training
 - <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/MedCandDGenCompdownload.pdf>

Key Compliance Requirements

- Have a way to anonymously report suspected or actual non-compliance for services provided to Navitus and a process for prompt investigation.
 - If you do not have a method for reporting, use our hotline at 855-673-6503.
 - This is also a False Claims Act requirement per 31 U.S.C. §3730(h).
- Check your employees and subcontractors against federal sources at minimum prior to hire/engagement and monthly thereafter:
 - HHS OIG List of Excluded Individuals and Entities
 - https://oig.hhs.gov/exclusions/exclusions_list.asp
 - GSA System for Awards Management – Search Page
 - <https://sam.gov/content/home>
- Make your policies and procedures are written and available for review.
- Have mechanisms to audit or monitor for compliance
- Have mechanisms for correction including sanctions or disciplinary action.

Additional FDR Obligations

Vendor



- Key Compliance Requirements
- Service Agreement

Vendor + FDR



- Key Compliance Requirements
- Service Agreement
- FDR Addendum
- FWA Attestation
- FDR Audit Evidence
- FDR Annual Checklist

Additional FDR Obligations

First Tier, Downstream and Related (FDR) Entities have additional obligations to demonstrate compliance specific to Medicare and Medicaid programs. This applies to both pharmacy and non-pharmacy vendors.

- FDR Addendum – this outlines additional contractual commitments and obligations required by CMS and is included in the service agreement.
- FWA Attestation – annually, every FDR is required to complete an attestation validating adherence to Key Compliance Requirements.
- FDR Audit Evidence – annually, any FDR may be selected for a formal audit of evidence demonstrating adherence to Key Compliance Requirements.
- FDR Annual Checklist – annually, any non-pharmacy FDR may be requested to complete this confirmation of compliance activities.

Additional Business Associate Obligations

Vendor



Key Compliance Requirements

Service Agreement

Vendor + BAA*



Key Compliance Requirements

Service Agreement

Business Associate Attestation

* This may be in addition to FDR requirements

Additional BAA Obligations

Vendors with a Business Associate Agreement (BAA) have additional obligations to demonstrate ongoing compliance with the Health Insurance Portability and Accountability Act (HIPAA) privacy and Security Rules. These are Vendors who are involved in handling, managing, or disclosing protected health information (PHI).

- BAA Attestation –annually, every FDR who is also a business associate is required to complete an attestation validating adherence to HIPAA requirements.
- Describe or provide feedback on any activity that is not being met in the BAA Attestation.

What About Offshore Subcontractors?

- The term “offshore” refers to any country that is not one of the fifty United States or one of the [United States Territories](#) (including American Samoa, Guam, Northern Marianas, Puerto Rico, and Virgin Islands).
 - Examples of countries that meet the definition of “offshore” include Mexico, Canada, Ireland, India, and Philippines.
- Subcontractors that are considered offshore can either be American-owned companies with certain portions of their operations performed outside of the United States or foreign-owned companies with their operations performed outside of the United States.
- Offshore subcontractors are doing work that provides support for or directly performs delegated services that are located in offshore countries, regardless of whether the workers are employees of American or foreign companies.

What About Offshore Subcontractors?

- You must ensure that your organization does not transfer Navitus' Medicare/Medicaid-related work without first having received express written consent from Navitus.
- We require that this information be provided to us within **15 calendar days** after an offshore subcontract is signed so we can provide the information to our Plan Sponsors.
- Plan Sponsors may need to provide additional notification to CMS or State Agencies where they are permitted to have data offshore. Not all Plan Sponsors may permit offshore support.
- You will need to conduct annual audits of offshore subcontractors and make audit results available upon request.

Need More Information?

- Check out our Vendor/FDR manual at <https://www.navitus.com/vendor-fdr>
- Email Navitus at FDR@navitus.com
- Call our Hotline at 1-855-673-6503

References

- Medicare Managed Care Manual Ch 21 and Prescription Drug Benefit Manual Ch 9
 - <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf>
- Guidelines for Constructing a Compliance Program for Medicaid Managed Care Organizations and PrePaid Health Plans
 - <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/FraudAbuseforProfs/Downloads/mccomplan.pdf> [Microsoft Word - MCCompliancePlan.doc \(cms.gov\)](#)
- DOJ Evaluation of Corporate Compliance Programs
 - <https://www.justice.gov/criminal-fraud/page/file/937501/download>
- US Sentencing Guidelines §8B2.1 Effective Compliance and Ethics Program
 - <https://guidelines.usc.gov/gl/%C2%A78B2.1>

Thank You.



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