First Tier, Downstream and Related Entity (FDR) Compliance Guide

NAVITUS
PHARMACY BENEFITS REINVENTED™

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As a pharmacy benefit manager (PBM), Navitus Health Solutions is committed to ensuring it is fully compliant with all laws, regulations and standards.

In addition, as a PBM that provides services on behalf of a Medicare Part D prescription drug plans, Navitus is a first-tier entity. In this role, we have been delegated certain responsibilities and must ensure that we and our participating network pharmacies, vendors and subcontractors (downstream and related entities) are all in compliance with the applicable laws, rules and regulations.

Being compliant with laws and regulations includes following guidelines for compliance issued by the Centers for Medicare and Medicaid Services (CMS) and the Office of Inspector General of the U.S. Department of Health and Human Services (HHS/OIG). These guidelines state that vendors and contractors, to whom we delegate part of our services, must follow the same compliance guidelines, laws, regulations and standards as Navitus, as long as those services are provided to or on behalf of Navitus.

In this guide, you will find compliance resources you need as a vendor, contractor or subcontractor to learn about Navitus' compliance requirements. The purpose of this Compliance Guide is to assist FDRs in understanding and meeting their compliance obligations under the Navitus Compliance Program. The FDR Handbook contains the CMS requirements and the steps you need to follow to comply as a downstream entity of Navitus Health Solutions. **Please review this guide to make sure you have internal processes to support your compliance with these requirements each calendar year.** To ensure ongoing compliance, Navitus conducts random audits, which request evidence of your compliance with the elements contained in this guide.

These resources include:

- Navitus Vendor Code of Conduct
- Information about the Navitus confidential reporting Hotline
- Compliance and Fraud and abuse reporting poster
- Information about training requirements and how to obtain a copy of the CMS Compliance and FWA training modules
- A copy of the mandatory attestation form and how to submit the annual form online

Our partnership ensures that Navitus continues to provide high quality service while adhering to the highest standards of ethics and compliance.

WHAT IS AN FDR?

The Centers for Medicare and Medicaid Services (CMS), in its regulatory guidance, refers to our contracted partners as First-Tier, Downstream, and related Entitles, or FDRs. (see 42 C.F.R. §423.501).

First Tier Entity: any party that enters into a written arrangement, acceptable to CMS, with an 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 MA program or Part D program.

Downstream Entity: 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 MAO or applicant or a Part D plan sponsor or applicant and a first tier entity. These written arrangements continue down all levels through to the ultimate provider of both health and administrative services.

Related Entity: any entity that is related to an MAO or Part D sponsor by common ownership or control and

(1) Performs some of the MAO or Part D plan sponsor's management functions under contract or delegation;

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

(3) Leases real property or sells materials to the MAO or Part D plan sponsor at a cost of more than $2,500 during a contract period

NAVITUS MEDICARE PART D COMPLIANCE PROGRAM

Navitus is committed to meeting the requirements of all applicable laws and regulations of the Medicare Part D programs. Our commitment to this is embodied in our standards of conduct titled the "Navitus Code of Conduct". The Code of Conduct is something each Navitus employee commits to uphold in his/her job and these standards are regularly reinforced with employees and Navitus-contracted participating pharmacies and vendors.

According to CMS rules and Navitus' contractual terms with our Medicare D plan sponsors, Navitus must implement a compliance program that is effective in preventing, detecting, and correcting Medicare Part D program noncompliance as well as program Fraud, Waste, and Abuse (FWA). The compliance program is evaluated regularly to ensure adherence to CMS' seven elements of an effective compliance program.

FDR COMPLIANCE REQUIREMENTS AND HOW TO MEET THEM

Navitus is committed to operating a PBM that meets the requirements of all applicable laws and regulations of the Medicare Advantage and Part D programs. As part of an effective compliance program, the Centers for Medicare and Medicaid Services (CMS) requires plan sponsors and their PBMs to ensure that any FDRs to which the provision of administrative or healthcare services are delegated are also in compliance with applicable laws and regulations.

The key compliance requirements for FDRs and recommendations for meeting those requirements are outlined below. Navitus provides a Non-Pharmacy FDR Annual Compliance and FWA Attestation or an NCPDP Participating Pharmacy Annual Compliance and FWA Attestation as appropriate for your organization to validate compliance with these requirements.

The recommendations provided in this Section for "How to Comply" below are suggestions and should not replace analysis by your organization in meeting your compliance obligations. Additionally, these recommendations are not intended to encompass all of your compliance obligations as these relate to the function(s) your organization may be performing under the Medicare Part D program only.

STANDARD OF CONDUCT AND COMPLIANCE POLICIES

REQUIREMENTS	HOW TO COMPLY
In order to communicate compliance expectations for FDRs, Standards of Conduct and policies and procedures must be distributed to FDRs' employees. Distribution must occur within 90 days of hire, when there are updates to the policies, and annually thereafter. Navitus makes Standards of Conduct and policies and procedures available to its FDRs. Alternatively, the FDR has comparable policies and procedures and Standards of Conduct of its own that it may use. *(Medicare Prescription Drug Benefit Manual Ch. 9 §50.1.3)*	You can distribute your organization's own Standards of Conduct and compliance policies and procedures to your employees or you may distribute the Navitus materials. Navitus makes its Vendor Code of Conduct available to FDRs in Appendix A of this Compliance Guide and also on the **Navitus Vendor FDR webpage at www.navitus.com**.

GENERAL COMPLIANCE AND FRAUD, WASTE AND ABUSE (FWA) TRAINING

REQUIREMENTS	HOW TO COMPLY

General Compliance Education - Plan sponsors must ensure that general compliance information is communicated to their FDRs including their PBM as a first tier entity. The plan sponsor's compliance expectations can be communicated through distribution of the Navitus Code of Conduct and/or compliance policies and procedures to FDRs' employees.
 	
(Medicare Prescription Drug Benefit Manual Ch. 9 §50.3.1)
 	
FWA Training - The PBM's employees (including temporary workers and volunteers), governing body members, as well as FDRs' employees who have involvement in the administration or delivery of Part D benefits must, at a minimum, receive FWA training within 90 days of initial hire (or contracting in the case of FDRs), and annually thereafter. PBMs must be able to demonstrate that their employees and FDRs have fulfilled these training requirements as applicable.
 	
(Medicare Prescription Drug Benefit Manual Ch. 9 §50.3.2)
	• Training
	  ○ Take the CMS Standardized FWA Training Module, available at http://www.cms.gov/MLNProducts.
	  ○ Use the CMS Standardized CMS General Compliance Training Module from 2019 at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/MedCandDGenCompdownload.pdf
	  ○ Provide training with content that is substantially similar to and addresses core concepts and topics of CMS Standardized General Compliance and FWA Training modules.
	  ○ If a pharmacy is completing a CMS/Medicare D oriented General Compliance and/or FWA training module mandated by another PBM, Plan Sponsor or health plan, that training may be used to satisfy this requirement.
	• Ensure that any of your employees, including temporary workers or volunteers, that support Navitus Medicare Part D programs complete the training within 90 days of hire and annually thereafter.
	• Maintain records of any Medicare general compliance and fraud, waste, and abuse training and education taken by your employees for 10 years. The records must demonstrate the date of the training, the topic, attendance, and certificates of completion and/or test scores, if applicable. Examples of proof of training may include copies of sign-in sheets, employee attestations and electronic certifications from the employees taking and completing the training.
	• If you are "deemed" for FWA training, you do not need to take the CMS Standardized FWA training. Organizations are "deemed" if they have met the FWA certification requirements through enrollment into Parts A or B of the Medicare program or through accreditation as a supplier of DMEPOS. However, Navitus must still communicate general compliance training to its employees. Navitus provides General Compliance information to you and your employees through the following methods:
	  ○ The FDR Compliance Guide;
	  ○ This FDR page of the Navitus website at www.navitus.com.

REPORTING MECHANISM FOR COMPLIANCE AND FWA ISSUES

REQUIREMENTS	HOW TO COMPLY

Plan sponsors must have a system in place to receive, record, respond to, and track compliance questions or reports of suspected or detected noncompliance or potential FWA from employees, members of the governing body, enrollees, and FDRs and their employees. Reporting systems must maintain confidentiality (to the greatest extent possible), allow anonymity if desired (e.g., through telephone hotlines or mail drops), and emphasize the plan sponsor's/FDR's policy of non-intimidation and non-retaliation for good faith reporting of compliance concerns and participation in the compliance program. FDRs that partner with multiple plan sponsors may train their employees on the FDR's reporting processes including emphasis that reports must be made to the appropriate PBM to forward to the appropriate plan sponsor.
 	
The methods available for reporting compliance or FWA concerns and the non-retaliation policy must be publicized throughout the sponsor's or FDR's facilities. Plan sponsors must make the reporting mechanisms user friendly, easy to access and navigate, and available 24 hours a day for employees, members of the governing body, and FDRs. It is a best practice for plan sponsors to establish more than one type of reporting mechanism to account for the different ways in which people prefer to communicate or feel comfortable communicating.
 	
(Medicare Prescription Drug Benefit Manual Ch. 9 §50.4.2)
	• Distribute the Navitus FDR Reporting Poster to your employees or post it in your facility. This will provide the required notifications regarding the availability of an anonymous reporting method and the Navitus policy prohibiting retaliation or retribution against anyone who reports suspected violations in good faith. This poster is in Appendix C of this Compliance Guide and is available on the **Vendor/FDR page of the Navitus website at www.navitus.com.**
	• If you partner with multiple Medicare plan sponsors, train your employees on your organization's reporting processes including an emphasis that reports must be made to the appropriate Medicare plan sponsor.
	• Notify your employees that they are **protected from retaliation** for False Claims Act complaints.
	• Below are suggested criteria for referring reported issues to Navitus. The list is not intended to be all inclusive. Any concerns about program noncompliance or suspected FWA should always be reported.
	  ○ Complaints or allegations that reference Navitus.
	  ○ Complaints from a Navitus member about quality of care received from a Navitus contracted provider or vendor.
	  ○ Complaints from Navitus members regarding access to care or services.
	  ○ Complainants wishing to appeal a Navitus coverage decision (medical or pharmacy) or to file a grievance about Navitus.
	  ○ HIPAA incidents or violations that impact Navitus members.
	  ○ Allegations that the complainant has been contacted by "someone" from Navitus requesting personal or medical information.
	  ○ Instances of alleged FWA.
	  ○ Instances where you become aware that an individual or entity involved with the Navitus has become excluded from participation in federal programs.

OIG AND GSA EXCLUSION SCREENING

REQUIREMENTS	HOW TO COMPLY
As a first tier entity, our Medicare D plan sponsors require that Navitus and their downstream entities review the DHHS OIG List of Excluded Individuals and Entities (LEIE list) and the GSA System for Award Management exclusion list (SAM) prior to the hiring or contracting of individuals and entities including any new employee, temporary employee, volunteer, consultant, governing body member, or FDR, and monthly thereafter. This is to ensure that none of these persons or entities are excluded or become excluded from participation in federal programs. Monthly screening is required to prevent inappropriate payment to pharmacies, vendors, and other entities that have been added to exclusions lists since the prior month. *(Medicare Prescription Drug Benefit Manual Ch. 9 §50.6.8)*	• Review the Department of Health and Human Services (DHHS) Office of Inspector General (OIG) List of Excluded Individuals and Entities (LEIE) at the time of hiring or contracting and monthly thereafter. The LEIE is available at: **http://oig.hhs.gov/exclusions/index.asp**. • Review the General Service Administration (GSA) System for Award Management (SAM) at the time of hiring or contracting and monthly thereafter. SAM is available at: **www.sam.gov/SAM**. • Be prepared to produce documentation that your employees and individuals and any entities referenced in the requirements with whom you contract have been checked timely against the exclusion lists.

DOWNSTREAM ENTITIES

REQUIREMENTS	HOW TO COMPLY
Plan sponsors are responsible for the lawful and compliant administration of the Medicare Part D benefits under their contracts with CMS, regardless of whether the plan sponsor has delegated some of that responsibility to FDRs, including their PBM. As a first tier entity, Navitus is monitored and audited by its Medicare Part D plan sponsors to ensure we are in compliance with all applicable laws and regulations, and to ensure that we are monitoring the compliance of the entities with which we contract ("downstream" entities). This monitoring includes an evaluation to confirm that the first tier entities are applying appropriate compliance program requirements to downstream entities with which the first tier entity contracts. *(Medicare Prescription Drug Benefit Manual Ch. 9 §50.6.6)*	If your organization subcontracts with other entities (external vendors to your organization and downstream entities to Navitus) to perform any of the services contractually delegated to your organization by Navitus for Medicare Part D programs, your organization must distribute materials and information to your downstream entities and monitor and audit their performance to ensure their compliance with applicable CMS requirements and the requirements in this Compliance Guide.

OFFSHORE SUBCONTRACTORS

REQUIREMENTS	HOW TO COMPLY
Medicare plan sponsors that work with offshore subcontractors to perform Medicare-related work that uses beneficiary protected health information (PHI) are required to provide CMS with specific offshore subcontractor information and complete an attestation regarding protection of beneficiary PHI. The term "offshore" refers to any country that is not one of the fifty United States or one of the United States Territories (American Samoa, Guam, Northern Marianas, Puerto Rico, and Virgin Islands). Examples of countries that meet the definition of "offshore" include Mexico, Canada, 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 provide services that are performed by workers located in offshore countries, regardless of whether the workers are employees of American or foreign companies. "Medicare-related work" encompasses what offshore contractors do when they receive, process, transfer, handle, store, or access beneficiary PHI while helping organizations such as Navitus and our pharmacies and vendors fulfill their Medicare Part D contract requirements. Examples of Medicare-related work includes claims processing, claims data entry services, scanning, software enhancement and troubleshooting, and any other situation where the offshore subcontractor may have access to beneficiary PHI. *(CMS Memo dated August 28, 2008: Offshore Subcontractor Data Module in HPMS)*	• **You must ensure that you do not engage in offshore subcontracts for any of Navitus' Medicare-related work without first having received expressed consent from Navitus Compliance Department.** CMS requires Medicare Part D Plan Sponsors to provide attestation to CMS within 30 calendar days after an offshore contract is signed. In the event Navitus approves an offshore subcontract and to ensure that the required attestations are provided to CMS timely, Navitus will request the information necessary for Plan Sponsors to complete the Offshore Subcontractor Data Module in HPMS (refer to Appendix C). 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. • Verify that any vendor maintains contractual agreements with those entities that include all required Medicare Part D Plan language and HIPAA privacy and security regulations as the vendor's Business Associate. • Ensure the offshore subcontractor maintains policies and procedures that protect beneficiary PHI. • Conduct annual audits of offshore subcontractors and make audit results available upon request from CMS.

RECORD RETENTION AND RECORD AVAILABILITY

REQUIREMENTS	HOW TO COMPLY
PBMs, as first tier and downstream entities, must comply with Medicare laws, regulations, and CMS instructions (422.504(i) (4)(v)), and agree to audits and inspection by CMS and/or its designees and to cooperate, assist, and provide information as requested, and maintain records a minimum of 10 years. *(Medicare Managed Care Manual Ch. 11 §100.4)* Plan sponsors are accountable for maintaining records for a period of 10 years of the time, attendance, topic, certificates of completion (if applicable), and test scores of any tests administered to their employees, and must require FDRs to maintain records of the training of the FDRs' employees. *(Medicare Prescription Drug Benefit Manual Ch. 9 §50.3.1)* CMS has the discretionary authority to perform audits under 42 C.F.R. 44 422.504(e)(2) and 423.505(e)(2), which specify the right to audit, evaluate, or inspect any books, contracts, medical records, patient care documentation, and other records of plan sponsors or FDRs (including PBMs and their downstream entities) that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract or as the Secretary of Health and Human Services may deem necessary to enforce the contract. Plan sponsors and FDRs must provide records to CMS or its designee. Plan sponsors should cooperate in allowing access as requested. Failure to do so may result in a referral of the plan sponsor and/or FDR to law enforcement and/or implementation of other corrective actions, including intermediate sanctioning in line with 42 C.F.R. Subpart O. *(Medicare Prescription Drug Benefit Manual Ch. 9 §50.6.11)*	• Maintain all records, reports, and supporting documentation that relate to the functions your organization is performing or providing under the Navitus Medicare Part D program for 10 years from the end of the calendar year. • Maintain records of any Medicare general compliance and FWA training and education taken by your employees for 10 years. The records must demonstrate the date of the training, the topic, attendance, and certificates of completion and/or test scores, if applicable. Examples of proof of training may include copies of sign-in sheets, employee attestations and electronic certifications from the employees taking and completing the training. • Be prepared to make your records available to Navitus as part of a Navitus audit or monitoring activity and to a Navitus plan sponsor in the event of a CMS program audit.

ONGOING AUDITING AND MONITORING

Navitus performs regular risk assessments, including an assessment of activities delegated to FDRs, which are used to guide the work and activities of the Compliance Program and to develop an annual audit plan. Navitus' monitoring activities are structured to regularly review normal operations and to confirm ongoing compliance using metrics and key performance indicators. Navitus also monitors federal lists to identify providers, pharmacies, and other individuals and entities that are excluded from participation in federal programs.

As an FDR that contracts with Navitus to provide Medicare-related administrative and healthcare services, you must ensure that compliance is maintained by your organization as well as your downstream and related entities. To ensure ongoing compliance, Navitus conducts random audits, which involve requesting evidence of your compliance with these requirements including:

- Documentation that your organization's Code of Conduct (or the Navitus Code of Conduct) and compliance policies were distributed within 90 days of hire, when there are updates, and annually thereafter;
- Evidence of completion of compliance and FWA training for employees within 90 days of hire and annually thereafter. Copies of the training materials will also be requested unless the free training from the CMS MLN website is utilized;
- Documentation showing OIG and GSA/SAM exclusion reviews were conducted prior to hire and monthly thereafter;
- Documentation of annual audits of any offshore subcontractors.

Please be familiar with these audit requirements and be prepared to produce the necessary documentation should it be requested by Navitus or CMS.

Appendix A:
Vendor Code of Conduct

Navitus Health Solutions is committed to full compliance with all applicable laws, regulations and contract requirements. In addition, we hold ourselves to the highest ethical standards on behalf of our clients and members. To help ensure we maintain our compliance and ethical standards, we work closely with our vendors and business partners.

Our vendors and business partners are important to our success and play a critical role in servicing our members, whether directly or indirectly. This Vendor Code of Conduct (Code) is provided to you as an easy way to communicate our expectations as your company fulfills the terms of the contract. This Code is a guide and does not include all possible activities. Please share with your employees and contact us if you have a question about an activity not included in this Code.

A print ready version of the Navitus Code of Conduct can be found on the Navitus website at www.navitus.com and clicking on the Vendor/FDR link at the bottom of the page.

Gifts and Business Gratuities

Navitus discourages you from providing any gifts, meals, entertainment or other business gratuities to Navitus employees, consultants or pharmacists. While we appreciate the occasional pen with your business name, items such as the following are not appropriate:

- Gifts or entertainment of any kind to any Navitus staff during the selection, negotiation or purchasing stages of a contractual arrangement.
- Gifts or entertainment that could be perceived as a bribe, payoff or advantage.
- Cash or cash-equivalents, such as checks, gift certificates/cards or stock.
- Gifts or entertainment that violate the law.

Conflicts of Interest

Conflicts of interest between a vendor and Navitus staff (or the appearance of a conflict) should be avoided. When an actual, potential or perceived conflict of interest occurs, that conflict must be disclosed, in writing to the Navitus employee who has the relationship with the vendor.

While Navitus employees may occasionally have secondary employment, no staff member may work for a vendor that has a contractual relationship with Navitus.

No Navitus employee may participate on the board of a vendor with whom Navitus does business.

Compliance with Laws

Vendors are expected to conduct their business activities in compliance with all applicable laws and regulations, including Medicare and Medicaid. Vendors are also expected to take appropriate action against any of its employees or subcontractors that have violated such laws.

Appendix A:
Vendor Code of Conduct

Privacy and Security

Many State and Federal privacy laws, such as the requirements of the Health Insurance Portability and Accountability Act (HIPAA) require Navitus and our vendors to maintain the privacy and security of patient information (PHI). If a vendor will have access to Navitus member PHI, the vendor is responsible for ensuring that all employees who provide services to Navitus are trained on HIPAA Privacy and Security Rules, and is expected to provide an annual attestation that such training has been completed. In addition, if vendor uses or discloses PHI on behalf of Navitus, the vendor will be expected to enter into a Business Associate Agreement.

Ineligible Persons and Vendors

Navitus will not do business with any vendor if it is, or any of its officers, directors or employees are excluded, debarred or ineligible to participate in any Federal health care program. To ensure no exclusion exists, Navitus vendors are expected to screen all employees, officers and directors against two Federal exclusion lists before hire or engagement and on a monthly basis thereafter. These lists are the U.S. Department of Health and Human Services, Office of Inspector General List of Excluded Individuals and Entities (LEIE) and the General Services Administration's Excluded Parties List Service (EPLS). Vendors are expected to provide an annual attestation that such exclusion screening has occurred.

Fraud, Waste and Abuse (FWA)

Navitus will investigate all allegations of FWA and, where appropriate, will take corrective action, including civil or criminal action. Vendors are expected to report any suspected acts of FWA regardless of the source or possible participants. Navitus has several methods for reporting including via confidential, toll-free hotline, email, or mail. All good-faith reporting is protected by the Navitus Non-Retaliation Policy. Our toll free Compliance Hotline number is **1-855-673-6503**.

Vendor Compliance Training

Navitus requires all vendors, including vendor employees, to participate in and complete general compliance and FWA training. The vendor must document and provide an annual attestation that training has been completed. Training can be completed using the CMS free training modules located on the CMS MLN website. In addition to compliance and FWA training, Business Associates and their employees must also complete annual HIPAA training. This HIPAA training can be completed using the vendor's training or by requesting a copy of the Navitus HIPAA training.

Business Record Retention

Navitus requires vendors to retain all records related to services provided to Navitus for ten (10) years. These records must be made available to Navitus or a government auditor in accordance with applicable laws, regulations and contract terms.

Appendix B:
Compliance Poster

Have a compliance or fraud concern?

Reports of possible non-compliance or fraud can be submitted to the Navitus Health Solutions Compliance Department in the following ways:

Vendors: fdr@navitus.com
All Others: SIU@navitus.com

1.855.673.6503

Navitus Health Solutions
Attention: Carrie Aiken, *Chief Compliance Officer*
361 Integrity Drive, Madison, WI 53717

Reports can be made anonymously and there can be NO retaliation against you for reporting suspected non-compliance in good faith.

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Appendix C:
Offshore Subcontractor Attestation

Enter your pharmacy name, name and title of person completing this form, and the date that you completed this attestation:
Name: **Title:** **Signature:** **Date:**
Please provide a copy to: Navitus Health Solutions, LLC, Pharmacy Network Development 1025 W Navitus Dr Appleton, WI 54913 You may also email credentials@navitus.com or fax the form to 866-808-4649.

Part I. Offshore Subcontractor Information	
Offshore Subcontractor Name:	
Offshore Subcontractor Country:	
Offshore Subcontractor Address:	
Describe Offshore Subcontractor Functions:	
State Actual Effective Date for Offshore Subcontractor: (Month, Day, Year: Example January 15, 2017)	

Part II. Precautions for Protected Health Information (PHI)	
Describe the PHI that will be provided to the offshore subcontractor:	
Discuss why providing PHI is necessary to accomplish the offshore subcontractor objectives:	
Describe alternatives considered to avoid providing PHI, and why each alternative was rejected:	

Appendix C:
Offshore Subcontractor Attestation

Part III. Attestation of Safeguards to Protect Beneficiary Information in the Offshore Subcontract		
Item	**Attestation**	**Response Yes\No**
I.1	Offshore subcontracting arrangement has policies and procedures in place to ensure that Medicare beneficiary PHI and other personal information remain secure.	
I.2	Offshore subcontracting arrangement prohibits subcontractor's access to Medicare data not associated with the sponsor's contract with the offshore subcontractor	
I.3	Offshore subcontracting arrangement has policies and procedures in place that allow for immediate termination of the subcontract upon discovery of a significant security breach	
I.4	Offshore subcontracting arrangement includes all required Medicare Part C and D language such as record retention requirements, compliance with all Medicare Part C and D requirements, etc.	

Part IV. Attestation of Audit Requirements to Ensure Protection of PHI		
Item	**Attestation**	**Response Yes\No**
II.1	Organization will conduct an annual audit of the offshore subcontractor	
II.2	Audit results will be used by the Organization to evaluate the continuation of its relationship with the offshore subcontractor	
II.3	Organization agrees to share offshore subcontractors audit results with CMS upon request	