



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

Vendor (FDR)	
Date Attestation Sent to FDR	

Section I: Background

CMS requires any organization or individual that contracts with WellSense Health Plan (WellSense) to provide administrative or healthcare service functions on behalf of WellSense as a First Tier, Downstream and Related Entities (FDR) to comply with various Centers for Medicare & Medicaid Services (CMS) program requirements, including but not limited to those outlined within Chapter 42 of the Code of Federal Regulations, Parts 422 and 423, also referred to as Medicare Parts C and D. Such entities are known as First Tier, Downstream and Related Entities (FDR).

Through this attestation, which you are required to complete in accordance with your agreement with WellSense, you affirm your organization’s compliance with the referenced Compliance Program requirement which assists WellSense in demonstrating effective communication and oversight.

Section II: Instructions to Complete Attestation

Please complete this attestation in its entirety, along with the applicable Appendices, and return within sixty (60) calendar days of receipt to Vendor.Management@bmchp-wellsense.org.

Questions on content or requests for additional information may be directed to the Medicare Compliance Officer via email at Michael.Comerford@bmchp-wellsense.org with a copy to Vendor.Management@bmchp-wellsense.org.

Section III: Annual FDR Attestation

Item #	Requirement	Please mark the appropriate box below to confirm compliance with each requirement	
		Yes	No
1	Written Policies, Procedures and Standards of Conduct: FDR has established internal compliance policies and procedures and Standards of Conduct that communicate the organization’s compliance expectations and CMS requirements. These documents include, but are not limited to, a policy of non-retaliation for reporting noncompliance or FWA. These policies and procedures and Standards of Conduct are distributed to employees and downstream entities within 90 days of hire/contracting and annually thereafter.		

Section III: Annual FDR Attestation (cont)			
Item #	Requirement	Please mark the appropriate box below to confirm compliance with each requirement	
		Yes	No
2	General Compliance Training: FDR conducts and documents general compliance training of employees and downstream entities within 90 days of hire/contracting and annually thereafter.		
3	Fraud Waste and Abuse (FWA) Training: Unless otherwise deemed by CMS, FDR conducts and documents FWA training of employees and downstream entities within 90 days of hire/contracting and annually thereafter.		
4	Screening for Excluded Individuals: FDR screens its employees, downstream entities and providers, if applicable, to ensure individuals/entities are not sanctioned debarred, suspended or excluded from participation in Medicare or Medicaid programs. FDR screens upon hire/contracting and at least monthly thereafter against the applicable exclusion lists including the federal Office of Inspector General List of Excluded Individuals and Entities (LEIE list) and, the System for Award Management (SAM). FDR notifies WellSense and takes appropriate action if an individual and/or entity has been identified as being excluded.		
5	Reporting Mechanism: FDR maintains a well-publicized system for reporting compliance questions, concerns or potential FWA. The reporting mechanism allows for anonymous reporting, maintains confidentiality to the greatest extent possible, is user-friendly, easy to access and navigate, and available 24 hours a day. FDR documents disciplinary action and corrective action taken to address noncompliance or FWA.		
6	HIPAA Privacy & Security: FDR ensures that employees and downstream entities agree to safeguard beneficiary privacy and confidentiality and assure accuracy of beneficiary health records pursuant to applicable laws. FDR affirms that its employees and downstream entities will comply with the confidentiality and enrollee record accuracy requirements, including: (1) abiding by all Federal and State laws regarding confidentiality and disclosure of medical records, or other health and enrollment information, (2) ensuring that medical information is released only in accordance with applicable Federal, Massachusetts or Hampshire law, or pursuant to court orders or subpoenas, (3) maintaining the records and information in an accurate and timely manner, and (4) ensuring timely access by enrollees to the records and information that pertains to them. FDR affirms that it has provided or required appropriate training and/or education on these subjects to its employees and downstream entities.		

Section III: Annual FDR Attestation (cont)

Item #	Requirement	Please mark the appropriate box below to confirm compliance with each requirement	
		Yes	No
7	Compliance with Law: FDR monitors functions, including overseeing those functions performed by FDR's downstream entities, to ensure compliance with WellSense contractual obligations and Medicare (and Medicaid) requirements, if applicable. FDR promptly reports any noncompliance to WellSense and will provide copies of any corrective action/remediation plans upon request.		
8	Conflict of Interest: FDR is free of any conflict of interest in administering or delivering Medicare or Medicaid program benefits to WellSense members.		
9	Availability of Records: FDR maintains all books, records and documents pertaining to WellSense operations, as well as documentation of compliance with all Medicare requirements, for at least ten (10) years. FDR will produce, and cause downstream entities to produce, records to support this attestation, for investigation, oversight or audit as needed, upon request.		
10	<p>Contracting with Downstream Entities: FDR agrees that if it decides to subcontract with other entities to perform any of the services contractually delegated to your organization to perform on behalf of WellSense, it is required to obtain permission from WellSense prior to subcontracting. Should approval be granted, FDR agrees to maintain ongoing oversight and monitoring of such activity to ensure downstream entities are complying with WellSense contractual obligations and CMS program requirements.</p> <p>Please attach a completed Appendix I detailing all downstream entities contracted by the FDR and return within sixty (60) calendar days.</p>		
11	<p>Offshore Activities: FDR contracts with an entity utilizing offshore services that involves processing, transferring, handling, storing or accessing Protected Health Information (PHI).</p> <p>If yes, please complete and return Appendix II for each offshore entity and return within sixty (60) calendar days.</p>		

Section IV: FDR Attestation Signature

As an authorized representative of FDR, I hereby attest that the information contained herein is true, correct and complete, and acknowledge that responses may be subject to audit by WellSense.

<i>Printed Name of Authorized FDR Representative</i>	<i>Date</i>
<i>Title of Authorized FDR Representative</i>	<i>Email address</i>
<i>Signature of Authorized FDR Representative</i>	<i>Telephone number</i>



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APPENDIX II – Offshore Activity

Vendor (FDR)	
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Instructions to Complete
Please complete this Appendix for each entity with which you contract that might utilize offshore services involving the processing, transferring, handling, storing or accessing Protected Health Information (PHI).

Part I: Offshore Subcontractor Information

Offshore Subcontractor Name	
Offshore Subcontractor Country	
Offshore Subcontractor Address	
Offshore Subcontractor Functions	
Proposed or Actual Effective Date for Offshore Subcontractor	

Part II: Precautions for Protected Health Information (PHI)

Requirement	FDR Response
Description of the PHI that will be provided to the Offshore Subcontractor	
Discussion of why providing PHI is necessary to accomplish the Offshore Subcontractor objectives	
Description of alternatives considered to avoid providing PHI, and why each alternative was rejected.	

Part III: Attestation of Safeguards to Protect Beneficiary Information in the Offshore Contract

Requirement	FDR Response
Offshore subcontracting arrangement has policies and procedures in place to ensure that Medicare beneficiary protected health information (PHI) and other personal information remains secure.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Offshore subcontracting arrangement prohibits subcontractor’s access to Medicare data not associated with the sponsor’s contract with the offshore subcontractor.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Offshore subcontracting arrangement has policies and procedures in place that allow for immediate termination of the subcontract upon discovery of a significant security breach.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Offshore subcontracting arrangement includes all required Medicare Part C and D language (e.g., record retention requirements, compliance with all Medicare Part C and D requirements, etc.)	<input type="checkbox"/> Yes <input type="checkbox"/> No

Part IV: Attestation of Audit Requirements to Ensure Protection of PHI

Requirement	FDR Response
Organization will conduct an annual audit of the offshore subcontractor.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Audit results will be used by the Organization to evaluate the continuation of its relationship with the offshore subcontractor.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Organization agrees to share offshore subcontractor’s audit results with CMS, upon request.	<input type="checkbox"/> Yes <input type="checkbox"/> No