VIVA HEALTH
A Member of UAB Health System

First Tier, Downstream and Related Entities (FDR) Frequently Asked Questions (FAQ) and Answers

I. FDR General Questions and Answers

1. What is a First Tier, Downstream and Related Entity (FDR)?
Answer: The Centers for Medicare & Medicaid Services (CMS) defines an FDR as follows:

First Tier Entity – any party that enters into a written arrangement, acceptable to CMS, with a Medicare Advantage (MA) 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 (refer to 42 CFR 423.501).

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 to the level of the ultimate provider of both health and administrative services (refer to 42 CFR 422.501).

Related Entity – any entity that is related to an MAO or Part D plan 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 contact period (refer to 42 CFR 423.501).

2. Why is an Attestation necessary?
Answer: CMS requires VIVA HEALTH to have oversight of our FDRs. Part of this oversight includes obtaining verification that each FDR is meeting its contractual obligations with VIVA HEALTH.

3. How often do I have to complete the Compliance Program and Offshore Subcontractor Attestation?
Answer: The Attestation is due annually each year as part of VIVA HEALTH's oversight of FDRs.

4. Who should I submit the Annual Compliance Program and Offshore Subcontractor Attestation to at VIVA HEALTH and who can I call with questions?
Answer: Please submit your Attestation, by mail, fax or email to VIVA HEALTH's Vendor Oversight Program Manager, Tanya Maddox. All contact information is listed at the bottom of this document.

II. HIPAA, Compliance and Fraud, Waste and Abuse (FWA) Training

5. Why does our organization have to provide HIPAA training for our employees?
Answer: A member's individually identifiable health information is very confidential and must be protected at all times. Federal and state laws require VIVA HEALTH and our contractors to also protect this information. Providing education to your employees helps ensure this data is protected.

6. Why is it necessary for our organization to provide general compliance and fraud, waste and abuse (FWA) training to our employees and contractors (downstream and related entities)?
Answer: CMS requires MAOs and Part D sponsors to ensure general compliance and FWA training and education is provided to their FDRs and that FDRs provide training to their employees as well as downstream and related entities. Effective 1/1/16, CMS required that all FDRs complete CMS' Compliance/FWA training module on the Medicare Learning Network (MLN), or content of such training at: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Fraud-Waste_Abuse-Training_12_13_11.pdf. As of 1/1/16, FDRs must maintain copies of the MLN training signature page as evidence of training completion.

7. Do I have to provide my own general compliance and FWA training to my employees and downstream and related entities?
Answer: If you have not developed general compliance and FWA training that meet all CMS requirements, you must provide VIVA HEALTH's training for these individuals/entities. You can contact the individual listed at the bottom of the Attestation to obtain more information on VIVA HEALTH's compliance or FWA training. Remember, effective 1/1/16, CMS required all FDRs to complete CMS' Compliance/FWA training as referenced in #6.
Recommendation: While it is not required for an FDR's governing body to receive CMS's Compliance/FWA training, VIVA suggests providing the training information for their review.

8. What topics must our general compliance and FWA training address?
Answer: Training must meet CMS requirements issued in Publication 100-16, Medicare Managed Care Manual, Chapter 21 and 100-18, Medicare Prescription Drug Benefit Manual, Chapter 9 (available at: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html). At a minimum, training must include:

1. Standards of Conduct (also referred to as Code of Conduct or Code of Ethics) demonstrating the organization's commitment to compliant, lawful and ethical conduct and written policies and procedures describing the operation of the compliance program;
2. The organization's commitment to comply with applicable federal and state laws;
3. Well publicized disciplinary standards;
4. Guidance for reporting compliance concerns;
5. Description for prompt response to compliance issues/concerns;

6. The organization's system for routine monitoring and identification of compliance risks; and
7. A statement that good faith reporting carries no retaliatory actions.

9. How often must I provide general compliance and FWA training for my employees and downstream and related entities?
Answer: Training must be provided within 90 days of initial hire/contract execution and annually thereafter.

10. Do I need to maintain documentation showing that our organization provided general compliance and FWA training for employees and downstream and related entities?
Answer: Yes. Evidence of training may include training logs, sign-in sheets, electronic acknowledgments, or other documentation that best demonstrates fulfillment of your training obligation. CMS requires training records to be maintained for at least 10 years. VIVA HEALTH and/or CMS may request evidence of training at any time.

11. Can an FDR be deemed (exempt) from having to provide general compliance and FWA training for its employees and downstream and related entities?
Answer: Only FWA training can be deemed for FDRs that meet the FWA certification requirements through enrollment into Parts A or B of the Medicare program or through DMEPOS accreditation. FDRs deemed from providing FWA training must still provide general compliance training and meet other CMS training requirements (see #7 for training requirements).

III. Offshore Subcontractors

12. What is an offshore subcontractor?
Answer: CMS considers MA organizations and PDP sponsors to be "contractors" with respect to CMS for the purposes of delivering Medicare Part C and Part D benefits. The term "subcontractor" refers to any organization that a sponsor contracts with to fulfill or help fulfill requirements in their Part C and/or Part D contracts. Subcontractors include all FDRs.

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, Germany, and Japan. Subcontractors that are considered offshore can be either 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 performed by workers located in offshore countries, regardless of whether the workers are employees of American or foreign companies.

13. Does our organization have to disclose offshore subcontractor information or offshore staff if the subcontractor or staff will be performing a function that supports our contract with VIVA HEALTH?
Answer: Yes. For the Annual Compliance Program and Offshore Subcontractor Attestation, FDRs must complete this section for offshore contractors or offshore staff

that will receive, process, transfer, handle, store, or access protected health information (PHI) of VIVA HEALTH members in oral, written, or electronic form. Examples of PHI include beneficiary name, birth date, address, social security number, health insurance claim number, patient identifiers, medical diagnosis, medical history, treatment records, type of provider visited, use of health care services, payment information, evidence of insurance coverage, or any information that could reasonably lead to the identification of a VIVA HEALTH member. For example, if an FDR contracts with and provides PHI for a VIVA HEALTH member to an offshore company in Mexico, then the FDR should disclose this information in Section III of the Annual Compliance Program and Offshore Subcontractor Attestation.

Examples of functions that involve an FDR sharing PHI with an offshore subcontractor or offshore staff include, but is not limited to: claim processing, claim data entry services, scanning paper claims to create electronic records, receiving medical data for interpretation, receipt of beneficiary calls, IT services where access to PHI is available, and any other situation where the offshore subcontractor may have access to beneficiary PHI.

14. If our organization plans to begin using a new offshore subcontractor or employing new offshore staff, or plans to change the functions that a current offshore subcontractor performs, what does VIVA HEALTH require in terms of notification and prior approval?
Answer: VIVA HEALTH requires you to provide written notice 60 days in advance of contracting with any new offshore subcontractor or employing offshore staff to perform a function related to your contract with VIVA HEALTH. Written notice should be made using the Annual Compliance Program and Offshore Subcontractor Attestation. Please note that VIVA HEALTH must approve, in advance, any sharing of PHI with offshore subcontractors or offshore staff for conducting a function related to your contract with VIVA HEALTH.

15. What type of auditing are FDRs required to perform for offshore subcontractors?
Answer: FDRs are responsible for ensuring that offshore subcontractors abide by all applicable Medicare Part C, Part D, and HIPAA requirements. FDRs have the discretion to determine the audit criteria that are important for continuing a relationship with an offshore subcontractor. CMS expects FDRs to adopt audit criteria substantial enough to ensure the appropriate protection of PHI. CMS suggests, but does not require, an on-site audit of offshore contractors. The purpose of an on-site audit is, in part, to observe whether PHI is handled appropriately on a day-to-day basis. FDRs may hire third-party audit organizations to conduct audits.

16. Has CMS provided any documents that cover the appropriate steps to address the risk of offshore contracting?
Answer: CMS has not endorsed any particular document on this topic; however, to familiarize MAOs and FDRs of the risks involved in offshore subcontracting, the Government Accountability Office's (GAO) Report titled "*Privacy: Domestic and Offshore Outsourcing of Personal Information in Medicare, Medicaid, and TRICARE"* is a helpful resource. You may download the report by visiting the GAO's website at www.gao.gov and entering GAO-06-676 in the search box.

IV. Medicare/Medicaid Exclusions and Debarment

17. Why is it necessary for our organization to verify that our employees or downstream and related entities are not excluded or debarred from participation in Medicare and Medicaid?

Answer: VIVA HEALTH's contract with CMS and the Alabama Medicaid Agency prohibits us from employing or contracting with any individual or entity that is excluded or debarred from participating in federal or state health care programs. This same requirement extends to VIVA HEALTH's FDRs and the FDRs downstream and related entities.

18. Who must we verify is not excluded or debarred from participation in Medicare and Medicaid?

Answer: All employees, temporary employees, volunteers, contract employees, consultants, , contractors, etc. that will be involved in, or have access to, any information related to the FDR's contract with VIVA HEALTH.

19. Where can I find a list of excluded individuals?

Answer: FDRs must check the following exclusion lists:

- U.S. Department of Health and Human Services (DHHS) Office of Inspector General (OIG) List of Excluded Individuals/Entities (LEIE) at http://oig.hhs.gov/exclusions/index.asp
- System for Award Management (SAM) at www.sam.gov (formerly General Services Administration – GSA)
- Alabama Medicaid Agency excluded individuals and entities at http://www.medicaid.alabama.gov/CONTENT/7.0_Fraud_Abuse/7.7_Suspended_Providers.aspx

20. How often do the exclusion/debarment checks have to be completed?

Answer: The checks must be completed initially before hire/contract execution and monthly thereafter.

21. Do I need to maintain documentation showing that our organization verified OIG and GSA?

Answer: Yes. Evidence of exclusion/debarment verification depends on the system used to conduct these screenings. Some FDRs use a system that screens both OIG and GSA websites while others go directly to the websites to verify exclusions/debarment. Regardless of the system or process you use, you must maintain documentation that best demonstrates fulfillment of your obligation to verify exclusions/debarment. Such evidence may include screen prints of the exclusion results, exclusion reports, etc. The evidence must clearly show the name of the individual/entity checked, the exclusion/debarment source verified, date of the verification, and the results of the check.

22. What should I do if an individual or entity shows up as excluded or debarred?

Answer: The individual or entity must be immediately removed from directly or indirectly servicing or accessing VIVA HEALTH's member information. You must also report this finding immediately to VIVA HEALTH.

V. Reporting FWA or Compliance Concerns to VIVA HEALTH

23. If our organization identifies a possible or confirmed FWA or compliance issue related to our direct or indirect services we provide to VIVA HEALTH, what should we do?
Answer: Report the issue to VIVA HEALTH promptly. You may either contact your VIVA HEALTH contact or you may report the incident to VIVA HEALTH's Compliance Officer at 205-558-7606. Our website also has a method for you to communicate your concerns to us anonymously. Please go to www.vivahealth.com/FDR for more information.

Your employees (and downstream and related entities) must be educated regarding how to promptly report incidents of FWA or compliance concerns. There cannot be any retaliation or retribution against anyone who reports a concern in good faith.

FDRs are expected to fully cooperate with VIVA HEALTH in our requests for information related to the incident and to assist in reporting the incident to CMS, OIG or other authorities, as applicable.

VI. Non-Compliance

24. What happens if our organization does not meet all the requirements addressed in our contract with VIVA HEALTH and that are required by CMS?
Answer: If areas of non-compliance are identified, VIVA HEALTH is required to take action to ensure the deficiency is corrected. Depending on the severity of the issue, these actions may include, but are not limited to, development of a correct action plan by your organization, increased monitoring, suspension or termination of your contract with VIVA HEALTH, self-reporting to CMS, etc. VIVA HEALTH is required to follow established CMS laws and regulations. These requirements are not optional for VIVA HEALTH or for our FDRs.

Should you have any questions regarding this FAQ or the requirements for FDRs, please contact:

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417 20th Street North, Ste. 1100, Birmingham, AL 35203;
(phone) 205-558-3283 or (fax) 205-449-7626.

Also, please visit our website for additional FDR resources at www.vivahealth.com/FDR.