VIVA HEALTH®

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

I. Introduction – VIVA HEALTH's Commitment to Compliance

VIVA HEALTH, Inc. requires and promotes integrity, and an ethical, efficient and compliant approach to the delivery of health care services and administrative/management services. We are committed to conducting our business with the highest ethical standards and in compliance with all applicable federal and state laws and regulations.

Code of Conduct

1. Be Honest **2.** Know the Rules **3.** Ask Questions **4.** Don't Be Afraid to Ask for Help
5. Admit Mistakes **6.** Report Concerns

Requirements for a Compliance Program

VIVA HEALTH is contracted with the Centers for Medicare & Medicaid Services ("CMS") as a Medicare Advantage Organization ("MAO") that provides coverage to Medicare beneficiaries for Medicare Parts A and B services as well as Part D prescription drug coverage.

Our contract with CMS requires that we maintain an effective Compliance Program as stated in the following CMS guidance:

- Title 42 of the Code of Federal Regulations ("CFR"), Parts 422 and 423 (referred to as "Parts C & D")
- Medicare Managed Care Manual, Chapter 21 – *Compliance Program Guidelines* and the Prescription Drug Benefit Manual, Chapter 9 – *Compliance Program Guidelines* (both manuals contain identical guidance) located at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf

Vendors Providing Cost-Effective Solutions

VIVA HEALTH has contracts with individuals and entities ("vendors") that possess expertise, skill and knowledge of their respective industries, trades or professions and that have the ability to provide efficient and cost-effective health care and/or administrative services. When a vendor provides a core health care and/or administrative service that is required of VIVA HEALTH under our contract with CMS, the vendor meets the definition of First Tier, Downstream and Related Entity ("FDR").

II. What is an FDR?

CMS defines an FDR as follows:

F. **First Tier Entity** - is party that enters into a written arrangement, acceptable to CMS, with a MAO to provide administrative services or health care services to Medicare-eligible individual's under the Medicare Advantage Program Part C and/or Part D program (e.g., vendors contracted with VIVA HEALTH to provide claim processing, utilization management, transportation, or other core healthcare and/or administrative functions).

D. **Downstream Entity** - is a party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with a MAO benefit below the level of the arrangement between a MAO and a First Tier Entity (e.g., vendors contracted with an FDR to help fulfill its contractual obligations to VIVA HEALTH). The written arrangements continue down to the level of the ultimate provider of services for both health and administrative functions.

R. **Related Entity** - means party that is related to a MAO by common ownership or control and:

1. Performs some MAO 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 at a cost of more than $2,500 during a contract period.

III. What is the Purpose of this FDR Compliance Guide?

This FDR Compliance Guide is being provided to you because you have been identified as an FDR for VIVA HEALTH. The Guide also contains expectations VIVA HEALTH requires of all FDRs.

You'll find a summary of requirements in this guide
Please use this document as a "quick reference" guide to understanding our expectations of your Compliance Program and to ensure that you have internal processes to support your Compliance Program.

IV. FDR Compliance Program Requirements

VIVA HEALTH is committed to ensuring our FDRs are in compliance with applicable laws, rules and regulations.

It is important that you follow these requirements
FDRs are expected to adhere to CMS Compliance Program requirements and VIVA HEALTH's standards when conducting business on VIVA HEALTH's behalf.

Compliance Program Elements
Your organization and your Downstream Entities (if any) must comply with CMS Compliance Program requirements as stated in your contract with VIVA HEALTH. These seven (7) elements ensure your Compliance Program meets CMS' standards:

- Element 1: Written Policies, Procedures and Standards of Conduct
- Element 2: Designating a Compliance Officer and Oversight of Compliance Program
- Element 3: Effective Training and Education
- Element 4: Effective Lines of Communication
- Element 5: Well-Publicized Disciplinary Standards
- Element 6: Effective System for Routine Monitoring and Identification of Compliance Risks
- Element 7: Prompt Response to Compliance Issues

ELEMENT 1: WRITTEN POLICIES, PROCEDURES AND STANDARDS OF CONDUCT

FDRs must provide written policies and procedures or Standards of Conduct to all employees providing administrative and/or health care services for VIVA HEALTH. FDRs must also ensure their Downstream Entities distribute appropriate policies and procedures or Standards of Conduct to their employees that address similar requirements.

These policies and procedures or Standards of Conduct should include the following information:

- FDRs commitment to comply with all applicable Federal and State standards;
- FDRs expectations of its employees' compliance with the policies or Standards;
- The FDRs Compliance Program operation;
- Appropriate guidance to employees and others on dealing with suspected, detected or reported compliance issues;
- Details on how employees should communicate compliance issues to appropriate compliance personnel;
- Description of how suspected, detected or reported compliance issues are investigated/resolved; and
- Non-intimidation and non-retaliation protections for individuals that make good faith reports of non-compliance related to its Compliance Program.

Such information must be distributed to FDR employees and contractors:

- Within 90 days of hire/contract; and
- Annually thereafter.

FDRs can determine the most effective method of distributing the policies and procedures or Standards of Conduct (e.g., via hardcopy at the time of hire/contract, via electronic copy, posting a copy on the FDR's intranet, etc.). An FDR must maintain documentation that demonstrates the information was distributed.

ELEMENT 2: DESIGNATING A COMPLIANCE OFFICER AND OVERSIGHT OF COMPLIANCE PROGRAM

Each FDR must designate a senior level employee to act as the Compliance Officer for its organization. The Compliance Officer must maintain responsibility for the implementation of the FDR's Compliance Program, including responding to reports of potential fraud, waste and abuse (FWA) and non-compliance. The Compliance Officer also ensures documentation is maintained related to the Compliance Program and is responsible for overseeing, developing, and monitoring corrective action plans.

The Compliance Officer must have direct access to the FDR's senior-most leader (typically the CEO or President/Owner) and/or the FDRs governing body (if applicable).

ELEMENT 3: EFFECTIVE TRAINING AND EDUCATION

FDRs must ensure their employees and Downstream Entities, assigned to provide administrative and/or health care services for VIVA HEALTH, complete training related to the functions performed for VIVA HEALTH. In addition, training must be provided on the topics listed in this section.

Compliance and Fraud Waste and Abuse (FWA) training
FDRs are responsible for general compliance and fraud, waste and abuse (FWA) training. Training must be provided:

- Within 90 days of hire/contract date; and
- At least annually thereafter.

Who should complete training?
Not every employee in the organization needs to complete compliance and FWA training. Below are examples of critical roles within an FDR that clearly ***should*** be required to fulfill the training requirements:

- Senior administrators or managers directly responsible for the FDR's contract with VIVA HEALTH (e.g., senior vice president, departmental managers, etc.)
- Individuals directly involved with establishing and administering the FDRs contract with VIVA HEALTH (e.g., individuals involved with clinical decisions or coverage decisions, processing appeals and grievances or enrollments/disenrollments, processing of pharmacy or medical claims, etc.)
- Individuals involved with decision-making authority that relate to the FDRs contract with VIVA HEALTH
- Individuals with job functions that place the FDR in a position to perform functions or make decisions that could result in the FDR not complying with CMS Compliance Program requirements or committing FWA

If you have questions about which employee positions within your organization should be required to take the training, please contact Viva Health's Manager of Privacy and Vendor Oversight, Tanya Maddox at tanyamaddox@uabmc.edu.

Compliance and FWA Training Content
If your organization does not have a Compliance/FWA training program you can utilize a nationally recognized training program such as American Health Insurance Plan (AHIP) or we can provide our training modules.

Privacy and Security Training
FDRs are required to protect **all** VIVA HEALTH member information. This not only includes Protected Health Information (PHI), but also includes Personally Identifiable Information (PII). Employees that have access to PHI and/or PII must receive HIPAA Privacy and Security training at the time of hire (not to exceed 90 days from date of hire) and annually thereafter. Privacy and Security training should address topics such as:

- Federal and state laws governing the confidentiality of PHI and PII
- When PHI and PII may be accessed, used and disclosed
- Safeguards for protecting the integrity, confidentiality, and availability of PHI and PII

Validation of Training Completion
FDRs must retain records of training completion on the topics listed previously. Evidence may include sign-in sheets/training logs (if classroom training is provided), electronic certificates/reports generated from the FDR's training system, etc.

VIVA HEALTH will confirm these training requirements have been met as part of our annual attestation process and during FDR audits, if applicable. To validate training completion, please ensure the following information is retained for a minimum of 10 years per CMS requirements:

- Employee names
- Dates of employment
- Dates of completion
- Results of test scores (if captured)
- Title of training
- Training content

ELEMENT 4: EFFECTIVE LINES OF COMMUNICATION

An FDR must maintain effective communication between its employees and its downstream entities. This should include "broadcasting" the name, contact and location information for its Compliance Officer and communicate the information to any downstream entities.

FDRs must adopt a policy of non-retaliation and/or non-intimidation against employees, including whistle-blowers, who report suspected misconduct in good faith.

FDRs much "advertise" to its employees, the policy of non-retaliation and non- intimidation.

How to report suspected compliance issues
FDR employees are expected to report any suspected issues of non-compliance or FWA to the FDR's designated Compliance Officer as well as using alternative reporting mechanisms (including anonymous reporting). This may include, but is not limited to, reporting via the FDR's website, compliance hotline, etc.

VIVA HEALTH provides additional reporting mechanisms for an FDR's employees: How to Report Ethics, Compliance & FWA Concerns. Please feel free to publicize this flyer to your employees, if applicable.

ELEMENT 5: WELL-PUBLICIZED DISCIPLINARY STANDARDS

FDRs must require their employees to adhere to the requirements of its Compliance Program. FDRs should provide examples for their employees of what constitutes non-compliant, unethical and/or illegal behavior that are in violation of the Compliance Program as well as publicizing disciplinary standards that will be enforced when non-compliance is identified. Some examples of the types of publication methods include:

- FDR's Intranet site;
- General compliance training; and
- Posters prominently displayed throughout employee work and break areas.

Enforcement of Disciplinary Standards
FDRs must be able to demonstrate that disciplinary standards are enforced timely, consistently, and in an effective manner. A disciplinary policy should state a time frame for enforcement of disciplinary action. Records pertaining to any disciplinary action in response to a compliance violation should be maintained for a period of 10 years.
FDRs must report any issue of non-compliance or FWA to VIVA HEALTH if the issue is in any way associated with the services performed on VIVA HEALTH's behalf.

ELEMENT 6: EFFECTIVE SYSTEM FOR ROUTINE MONITORING AND IDENTIFICATION OF COMPLIANCE RISKS

VIVA HEALTH is ultimately responsible for fulfilling the terms and conditions of our contract with CMS. If any function is performed by an FDR, CMS requires monitoring and/or auditing of these functions to ensure such functions are performed in accordance with applicable laws and regulations.

FDRs must perform exclusion screenings.
Federal law prohibits Medicare, Medicaid and other federal health care programs from paying for items or services provided by an individual or entity excluded from participation in these federal programs.

FDRs must screen employees (permanent and temporary), volunteers, consultants, governing body members, contractors and downstream entities against the following exclusion/debarment sources prior to employing or contracting with the employee/contractor and monthly thereafter:

- Office of Inspector General (OIG): https://exclusions.oig.hhs.gov/
- System for Award Management (SAM): https://sam.gov/content/home

FDRs must maintain evidence they checked these exclusion sources for a minimum of 10 years. VIVA HEALTH requires, at a minimum, an annual attestation that all employees were appropriately screened.

You're not alone! We're also required to check these exclusion sources prior to hiring or contracting with individuals/entities and monthly thereafter.

You must take action if an individual/contractor is on the exclusion list.
If any individual or entity performing services for VIVA HEALTH is on the OIG or SAM exclusion list, you must immediately remove them from working directly or indirectly with VIVA HEALTH's business and notify us as soon as possible.

CMS Preclusion List Screening of Contracted Providers
FDRs must screen their contracted providers/prescriber's against the CMS Preclusion List, on a monthly basis. If you contract with providers/prescriber's, please contact VIVA HEALTH (see Section X below) for more information. If a provider/prescriber is on the Preclusion List, you must advise VIVA HEALTH immediately and ensure the provider/prescriber is removed from providing any services to VIVA HEALTH members.

For more information: https://www.cms.gov/medicare/provider-enrollment-and-certification/preclusion-list.

Avoiding a Conflict of Interest
A conflict of interest (COI) exists when the interests of an FDR or its employees influence or appear to influence their ability to make objective decisions in the course of the FDR job duties and/or responsibilities. FDRs and its employees must avoid a COI at all times. If a potential COI arises, the activity must be reported to the the FDR's Compliance Officer. If a COI relates directly to VIVA HEALTH's business, this must be reported to VIVA HEALTH immediately.

ELEMENT 7: PROMPT RESPONSE TO COMPLIANCE ISSUES

Reporting compliance concerns and/or FWA to VIVA HEALTH
There are a number of ways to report suspected or detected non-compliance or potential FWA to VIVA HEALTH. You can find the reporting mechanisms in the VIVA HEALTH "How to Report Ethics, Compliance and FWA Concerns" flyer at How to Report Ethics, Compliance & FWA Concerns.

You can share the flyer with your employees or Downstream Entities, if applicable. You can also keep it as a reference tool and use your own internal process for reporting and collecting these issues. If you choose to use your own process, make sure that any issues of non-compliance and/or FWA are reported in a timely manner to VIVA HEALTH.

FDRs must adopt and enforce a zero-tolerance policy for retaliation or intimidation against anyone, including whistleblowers, who report suspected misconduct in good faith. Any issues of detected non-compliance or potential FWA must be investigated in a timely manner and reported to the appropriate parties.

Corrective Action Plans
You must notify VIVA HEALTH immediately if non-compliance is identified related to the functions you provide for VIVA HEALTH. You may be required by VIVA HEALTH to conduct a root cause analysis and implement a Corrective Action Plan (CAP). The CAP must contain the following:

- Date non-compliance identified
- Root cause
- Period of non-compliance
- How the non-compliance was identified
- Issue of non-compliance
- Corrective action (including dates and key milestones)

VIVA HEALTH provides a CAP template and instructions to assist FDRs in documenting non-compliance and corrective actions. You can find the instructions and template at:

- CAP Template - https://www.vivahealth.com/Download.aspx?ID=25705
- CAP Template Instructions - https://www.vivahealth.com/Download.aspx?ID=25704

VIVA HEALTH expects FDRs to take action on all issues of non-compliance and FWA timely. This includes timely implementation of disciplinary actions, when applicable, to prevent recurrence of non-compliance.

V. Routine Monitoring and Auditing

VIVA HEALTH routinely monitors and periodically audits all First Tier Entities. This helps us ensure compliant administration of services under our contract with CMS and helps us ensure compliance with applicable laws and regulations. FDRs must cooperate and participate in monitoring and auditing activities.

First Tier Entities are also responsible for self-monitoring/auditing the functions they provide for VIVA HEALTH. If a First Tier Entity contracts with other individuals/entities to provide administrative and/or health care services to help fulfill its obligations to VIVA HEALTH, the First Tier Entity must monitor/audit the Downstream Entity to ensure it performs such functions in accordance with all applicable laws and regulations and in accordance with the First Tier Entities' contract with VIVA HEALTH. The First Tier Entity must also ensure its contracts with Downstream Entities contain CMS-required provisions.

If FDR functions are not in compliance with applicable laws and regulations, or in compliance with the terms of its contract with VIVA HEALTH, we will require the FDR to develop and submit a CAP (as referenced above).

VI. Offshore Operations and CMS Reporting

All work performed by FDRs on VIVA HEALTH's behalf must be performed within the United States and its territories (including America Samoa, Guam, Northern Marianas, Puerto Rico, and Virgin Islands). An FDR may request approval in advance from VIVA HEALTH to utilize employees or contractors located outside the United States. We refer to work being performed outside the United States and its territories as being "offshore."

If VIVA HEALTH approves a requested offshore arrangement, VIVA HEALTH must self-disclose the offshore arrangement to CMS. FDRs must also sign an attestation annually as to how it will oversee the offshore functions.

VII. Additional Standards for Conducting Services

In addition to meeting the CMS Compliance Program requirements, VIVA HEALTH also expects FDRs to:

- Maintain current federal, state and local licenses and permits required for the operation of the FDR's business or profession.
- Ensure that services provided for VIVA HEALTH are performed in a competent, timely, efficient, professional, and skillful manner as well as in compliance with applicable laws, regulations and the terms of its agreement with VIVA HEALTH.
- Ensure services provided for VIVA HEALTH are done so in a highly ethical manner and in compliance with the FDR's Standards of Conduct.
- Ensure services provided for VIVA HEALTH are conducted in an alcohol and drug-free workplace. FDR shall prohibit the unlawful manufacture, distribution, dispensation, possession or use of alcohol, illegal drugs, and/or drug paraphernalia at the workplace or while conducting any aspect of services for VIVA HEALTH.
- Prohibit unacceptable and unethical behaviors by individuals and entities providing services for VIVA HEALTH.

VIII. FDR Attestation Requirements

FDRs must maintain evidence of compliance with the requirements listed in this Guide for ***no less than 10 years***. Each year, an authorized representative from your organization must attest to your compliance with these requirements. An FDR's authorized representative is an individual who is ultimately responsible for assuring your organization provides services for VIVA HEALTH in a complaint manner.

An authorized representative could include your Compliance Officer, a Chief Executive Officer, Chief Operations Officer or someone in a similar position.

IX. What if an FDR Fails to Comply?

If an FDR fails to meet any of these Compliance Program requirements, this puts VIVA HEALTH and our members at risk and may lead to:

- Development of a corrective action plan (CAP)
- Additional monitoring/auditing
- Monetary penalties
- Termination of your contract with VIVA HEALTH

VIVA HEALTH's response to issues of non-compliance will depend on the severity of the compliance issue. If an FDR, VIVA HEALTH, CMS or any regulatory oversight agency identifies areas of non-compliance performed by an FDR, it must take prompt action to correct the issue and prevent it from happening again.

X. Questions or Comments?

If you have any questions regarding this Guide or the CMS Compliance Program requirements, please contact Tanya Maddox, Manager of Privacy and Vendor Oversight, as follows:

- Email: tanyamaddox@uabmc.edu
- Phone: 205-558-3283
- Address: 417 20th Street North, Ste. 1100, Birmingham, AL 35203