FIRST TIER, DOWNSTREAM, AND RELATED ENTITIES (FDR) GUIDE

Updated June 2024

Metro Plus Health

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MESSAGE FROM THE PRESIDENT AND CEO

MetroPlus Health Plan (MetroPlusHealth) is committed to providing quality care and service. As such, it has partnered with various entities to assist with honoring its contracts with the Centers for Medicare and Medicaid Services (CMS) and the New York State Department of Health (DOH). Our contractual agreement with you has identified you as a first-tier entity who must comply with these requirements. As you may subcontract with others to assist in your agreement with MetroPlusHealth, those providers are our downstream entities. On an ongoing and annual basis, we are required to ensure that you, and our downstream entities, meet our compliance program requirements, as well as all contractual obligations.

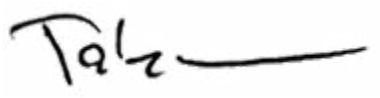
Included in the annual compliance program are:

- ✓ General compliance and fraud, waste, and abuse (FWA) training
- ✓ Compliance policies and procedures, such as Code of Conduct
- ✓ Office of Inspector General, General Services Administration, Office of Medicaid Inspector General exclusion, preclusion list and prohibited relationships screenings
- ✓ Maintenance of sufficient information Privacy Protocols

Noncompliance with these and other requirements may result in the revocation of the delegated activities for which you are contracted.

Please refer to the enclosed information to assist you in meeting your obligations. We value your partnership and thank you for your commitment to providing the highest quality of care and services to our members!

If you have questions or concerns, please contact us at **delegationoversight@metroplus.org**.



Talya Schwartz, MD
President and CEO
MetroPlusHealth

DEFINITIONS

Abuse includes actions that may, directly or indirectly, result in unnecessary costs to the Medicare Program, improper payment, payment for services that fail to meet professionally recognized standards of care, or services that are medically unnecessary. Abuse involves payment for items or services when there is no legal entitlement to that payment and the provider has not knowingly and/or intentionally misrepresented facts to obtain payment. Abuse cannot be differentiated categorically from fraud because the distinction between "fraud" and "abuse" depends on specific facts and circumstances, intent and prior knowledge, and available evidence, among other factors.

Affected Individuals means all persons who are affected by the required provider's risk areas including the required provider's employees, the chief executive and other senior administrators, managers, contractors, agents, subcontractors, independent contractors, and governing body and corporate officers.

Authorized Representative is an employee or affiliated party of a company who has responsibility directly or indirectly for all employees, contracted staff, providers/practitioners, and vendors who provide healthcare and/or administrative services for MetroPlusHealth.

Downstream Entity is any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the Medicare Advantage (MA) benefit or Part D benefit, below the level of the arrangement between a Medicare Advantage Organization (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. (See, 42 C.F.R. §, 423.501).

FDR means First Tier, Downstream or Related Entity.

First Tier Entity is any party that enters into a written arrangement, acceptable to CMS, with an 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. (See, 42 C.F.R. § 423.501).

Fraud is knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any health care benefit program or to obtain (by means of false or fraudulent pretenses, representations, or promises) any of the money or property owned by, or under the custody or control of, any health care benefit program. 18 U.S.C. § 1347.

FWA means fraud, waste, and abuse.

GSA means General Services Administration

OIG is the Office of the Inspector General within the United States Department of Health and Human Services (DHHS). The Inspector General is responsible for audits, evaluations, investigations, and law enforcement efforts relating to DHHS programs and operations, including the Medicare program.

OMIG means Office of Medicaid Inspector General.

Related entity means 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. (See, 42 C.F.R. §423.501).

TPMO (Third Party Marketing Organizations) organizations and individuals, including independent agents and brokers, who are compensated to perform lead generation, marketing, sales, and enrollment related functions as a part of the chain of enrollment.

DEFINITIONS (CONT)

Waste is the overutilization of services, or other practices that, directly or indirectly, result in unnecessary costs to the Medicare program. Waste is generally not considered to be caused by criminally negligent actions but rather the misuse of resources.

WHAT IS AN FDR?

Although the initials "FDR" stand for First Tier, Downstream and Related Entities (see definitions), you will find that the term is used for any vendor with whom health plans have delegated administrative or health care service functions relating to their Medicaid, CHIP and Medicare Parts C and D contracts.

Below are examples of functions that relate to the health plan's Medicare Parts C and D contracts:

- ✓ Sales and marketing
- ✓ Utilization management
- ✓ Quality improvement
- ✓ Applications processing
- ✓ Enrollment, disenrollment, membership functions
- ✓ Claims administration, processing, and coverage adjudication
- ✓ Appeals and grievances
- ✓ Licensing and credentialing
- ✓ Pharmacy benefit management
- ✓ Hotline operations
- ✓ Customer service
- ✓ Bid preparation
- ✓ Outbound enrollment verification
- ✓ Provider network management
- ✓ Processing of pharmacy claims at the point of sale
- ✓ Negotiation with prescription drug manufacturers and others for rebates, discounts, or other price concessions on prescription drugs
- ✓ Administration and tracking of enrollees' drug benefits, including TrOOP balance processing
- ✓ Coordination with other benefit programs such as Medicaid, state pharmaceutical assistance or other insurance programs
- ✓ Entities that generate claims data, and
- ✓ Health care services

Under Medicaid guidelines a vendor is classified as first tier entity if the following functions are performed:

- ✓ Maintenance of the books and records
- ✓ Disposition of assets and the incurring of liabilities normally associated with the day-to-day operations of the MCO
- ✓ Implementation of policies affecting the delivery of health care services (claims payment)
- ✓ Implementation of the MCO's budgets and provision for annual audits quality assurance
- ✓ Utilization review activity, quality assurance and/or quality improvement
- ✓ Special investigations unit

If you have been delegated any of the above functions, you are a first-tier vendor. First tier and related entities may contract with downstream entities to fulfill their contractual obligations to a health plan. For example, a field marketing organization (first tier entity) may contract with a smaller brokerage firm downstream entity to sell the health plan's Medicare Parts C and D products. That smaller brokerage firm may further contract with individual sales agents (downstream entities) to perform the day-to-day sales work.

A related entity may also be either a first-tier entity or a downstream entity.

COMPLIANCE PROGRAM REQUIREMENTS

Medicare, Medicaid, and CHIP Participation Compliance Program Requirements
(18 NYCRR 521) (42 CFR Parts 405, 417, 422, 423, 460, 498, 42 CFR §§ 438.608(a)(1), 457.1285)

It is important that our first-tier entities are in compliance with applicable laws, rules, and regulations. Although we contract with first tiers to provide administrative services for our plans, in the end MetroPlusHealth is responsible for fulfilling the terms and conditions of our contract with CMS and DOH and meeting applicable program requirements.

Therefore, our first tiers are responsible for complying with program requirements to the extent related to their contracted role and responsibilities within the provider's identified risk area, and must ensure that their subcontractors (MetroPlusHealth's downstream entities), which are used for our products, also comply with applicable laws, and regulations, including the requirements in this guide.

According to (18 NYCRR 521) (42 CFR Parts 405, 417, 422, 423, 460, 498, 42 CFR §§ 438.608(a)(1), 457.1285), the program requirements consist of having a Compliance Program. The Compliance Program entails the following elements:

1. Written policies, procedures, and standards of conduct that:
   - Provide guidance on how to deal with potential compliance issues
   - Identify how to communicate compliance issues to appropriate personnel
   - Describe how compliance issues are investigated and resolved
   - Describe sanctions for non-compliance
   - Sets forth a policy on non-intimidation and non-retaliation for good faith participation in the compliance program
2. Designating a compliance officer and compliance committee
3. Conducting effective training and education
4. Developing effective lines of communication
5. Conducting internal monitoring and auditing including a system for routine identification of compliance risk areas
6. Enforcing standards through well-publicized disciplinary guidelines
7. Responding to compliance issues and undertaking corrective action

While CMS has removed the requirement for FDRs to complete its general compliance and FWA training, it does not exempt the Plan from ensuring that FDRs have an effective compliance program. Specifically, CMS states, "We will continue to hold sponsoring organizations accountable for failures of their FDRs to comply with Medicare program requirements, even with this change." Therefore, we will expect our first-tier entities to implement an effective compliance program designed to:

1. Prevent, detect, and correct Medicare, Medicaid and CHIP non-compliance, fraud waste and abuse, and address improper conduct in a timely and well-documented manner
2. Provide training and education for its employees (including temporary staff, volunteers, consultants, governing body members and downstream entities (subcontractors). The training and education must be completed within 90 days of hire or contracting, and at least annual thereafter.
3. Provide employees including temporary staff, volunteers, consultants, governing body members and downstream entities (subcontractors) the code of conduct within 90 days of contracting and at least annual thereafter

Your organization must maintain a log of employees who are required to take the training, the names and dates for employees who completed the training and the materials used for training and documentation that the code of conduct was distributed. This information must be maintained for ten (10) years from the final date of the Contract period or from the date of completion of any audit, whichever is later, and must be available upon request.

First tiers are responsible for ensuring that delegated activities comply with NYS and CMS requirements as well as any applicable Medicaid, CHIP and/or Medicare laws and regulations, and any CMS guidance. Failure to comply can lead to a corrective action plan, partial or full revocation of delegated activities, termination of contract, actions as recommended by the MetroPlusHealth Audit and Compliance Committee of the Board of Directors and escalation to senior leadership at the MetroPlusHealth and the First-tier entity. A corrective action plan will be issued in accordance with MetroPlusHealth's Corrective Action Plan (CAP) policy. First tiers must correct the deficiency, detail the elements of any corrective action, and provide supporting documentation proving compliance. CAPs actions range from policy modifications all the way to termination of the Delegated Vendor's contract. The type of action taken by the Plan will depend on both the severity of the deficiency identified and the Vendor's attempt to remedy the deficiency.

Furthermore, CMS and DOH has the right to inspect, evaluate and audit an FDRs documentation associated with the delegate activity.

Exclusion and Sanctions Screening

(Medicare Managed Care Manual Ch. 21 §50.6.8)

(Medicaid Managed Care/Family Health Plus/HIV Special Needs Plan/Health and Recovery Plan Model Contract, Section 18)

(Managed Long Term Care Partial Capitation (MLTC) Contract Article VIII, F,3, o)

(CHIP NYSOH Contract, Section 21.5 Excluded Providers)

Federal law prohibits Medicare, Medicaid, CHIP and other federal health care programs from paying for items or services provided by a person or entity excluded from participation in these federal programs. Exclusion screenings must be performed on individuals, entities, and providers for those first-tier entities with a provider network.

Individuals and Entity Screenings

Your organization must perform individual, and entity checks for all employees, board members, vendors, and contractors prior to hire against exclusion lists mentioned below for each line of business to ensure that no individual is excluded or becomes excluded.

Medicare screening requirements:

- ✓ Office of Inspector General (OIG) – List of Excluded Individuals and Entities (OIG LEIE)
- ✓ General Services Administration's (GSA) System of Awards Management (GSA SAM)

Medicaid, CHIP and MLTC screening requirements:

- ✓ New York State OMIG Exclusions List
- ✓ Office of Inspector General (OIG) – List of Excluded Individuals and Entities (OIG LEIE)
- ✓ General Services Administration's (GSA) System of Awards Management (GSA SAM)
- ✓ Social Security Administration's Death Master File (SSDM)
- ✓ National Plan and Provider Enumeration System (NPPES)

In addition, your organization must perform individual, and entity checks for all employees, board members, vendors, and contractors **monthly** against exclusion lists mentioned below to ensure that no individual is excluded or becomes excluded from Medicare and Medicaid.

Medicare screening requirements:

- ✓ Office of Inspector General (OIG) – List of Excluded Individuals and Entities (OIG LEIE)
- ✓ General Services Administration's (GSA) System of Awards Management (GSA SAM)

Medicaid, CHIP and MLTC screening requirements:

- ✓ New York State OMIG Exclusions List
- ✓ Office of Inspector General (OIG) – List of Excluded Individuals and Entities (OIG LEIE)
- ✓ General Services Administration's (GSA) System of Awards Management (GSA SAM)
- ✓ Office of Foreign Asset Control (OFAC)

Provider Screenings

For those first-tier entities with a provider network, your organization must perform screenings for providers at **credentialing and recredentialing** to ensure that they are not listed in federal, or state exclusion or sanctions databases listed below.

Medicare screening requirements:

- ✓ Office of Inspector General (OIG) – List of Excluded Individuals and Entities (OIG LEIE)
- ✓ General Services Administration's (GSA) System of Awards Management (GSA SAM)
- ✓ Centers for Medicare and Medicaid Preclusion List

Medicaid, CHIP, and MLTC screening requirements*:

- ✓ New York State OMIG Exclusions List
- ✓ Office of Inspector General (OIG) – List of Excluded Individuals and Entities (OIG LEIE)
- ✓ General Services Administration's (GSA) System of Awards Management (GSA SAM)
- ✓ Social Security Administration's Death Master File (SSDM)
- ✓ National Plan and Provider Enumeration System (NPPES)
- ✓ Office of Foreign Asset Control (OFAC)* (not a Medicaid requirement)

In addition, your organization must perform screenings for all providers **monthly** to ensure that they are not listed in federal, or state exclusion or sanctions databases listed below.

Medicare screening requirements:

- ✓ Office of Inspector General (OIG) – List of Excluded Individuals and Entities (OIG LEIE)
- ✓ General Services Administration's (GSA) System of Awards Management (GSA SAM)
- ✓ Centers for Medicare and Medicaid Preclusion List

Medicaid, CHIP, and MLTC screening requirements*:

- ✓ New York State OMIG Exclusions List
- ✓ Office of Inspector General (OIG) – List of Excluded Individuals and Entities (OIG LEIE)
- ✓ General Services Administration's (GSA) System of Awards Management (GSA SAM)
- ✓ Office of Foreign Asset Control (OFAC)* (Not a Medicaid requirement)

For those first-tier entities with non-participating providers, screenings must be performed upon or no later than 30 days of first claim payment against the exclusion lists mentioned below that no individual is listed in federal or state exclusion or sanction databases.

Medicare screening requirements:

- ✓ Office of Inspector General (OIG) – List of Excluded Individuals and Entities (OIG LEIE)
- ✓ General Services Administration's (GSA) System of Awards Management (GSA SAM)
- ✓ Centers for Medicare and Medicaid Preclusion List

Medicaid, CHIP, and MLTC screening requirements*:

- ✓ New York State OMIG Exclusions List
- ✓ Office of Inspector General (OIG) – List of Excluded Individuals and Entities (OIG LEIE)
- ✓ General Services Administration's (GSA) System of Awards Management (GSA SAM)
- ✓ Social Security Administration's Death Master File (SSDM)
- ✓ National Plan and Provider Enumeration System (NPPES)
- ✓ Office of Foreign Asset Control (OFAC)* (Not a Medicaid requirement)

If excluded individuals are identified, you must notify MetroPlusHealth of the excluded individual's name and exclusion date immediately. Also, you must immediately remove the person from work directly or indirectly related to MetroPlusHealth. You should be prepared to produce evidence that your employees and any entities with whom you contract have been checked against the exclusion lists timely.

Fraud, Waste and Abuse and Non-Compliance

Mechanisms for Reporting Suspected Fraud, Waste and Abuse and Non-Compliance (Medicare Managed Care Manual Ch. 21 § 50.4.2)
Section 6032 of the Federal Deficit Reduction Act of 2005

As part of Section 6032 of the Federal Deficit Reduction Act of 2005, MetroPlus requires that FDRs have policies and procedures to prevent and detect any fraud, waste, or abuse in its organization.

MetroPlusHealth is dedicated to helping prevent health care fraud and investigates all allegations of fraud, waste, or abuse. Fraud includes member fraud, provider fraud, employee fraud and vendor fraud. Common methods of FWA include fabrication of claims, duplicate claim submissions and falsification of records. There are many indicators of fraud, which, if noticed, should be brought to the attention of MetroPlusHealth. The most common indicators include, but are not limited to:

- ✓ Reluctance or failure to submit medical records when requested
- ✓ Claims for more than one pharmacy for the same member in a short period of time

- ✓ Inconsistency between services billed and medical history
- ✓ Provider advertisement for free services, drugs, supplies, or durable medical equipment

If you suspect fraud, you may contact MetroPlusHealth confidentially in the following ways:

- ✓ Call: 888.245.7247 (In reporting via our 24/7 confidential hotline, you are able to remain anonymous)
- ✓ Write: Office of Corporate Compliance
  MetroPlusHealth Plan
  50 Water Street, 7th Floor
  New York, NY 10004
- ✓ E-Mail: Compliance Department at **fraud@metroplus.org**

You should adopt, widely publicize, and enforce a no-tolerance policy for retaliation or retribution against any employee who in good faith reports suspected FWA. Your employees must be notified that they are protected from retaliation for False Claims Act complaints, as well as any other applicable anti-retaliation protections. If you do not maintain a confidential FWA and compliance reporting mechanism, you must distribute and widely publicize the MetroPlusHealth Compliance Confidential Hotline to encourage reporting potential FWA and compliance issues that involve MetroPlusHealth.

Overpayments

Depending on the delegated administrative or health care service function(s) you perform for MetroPlusHealth, you are required to establish policies and procedures for your network of providers and subcontractors, informing them of their obligation to report, return and explain overpayments to the appropriate government agency within sixty (60) days of identification. Once an overpayment has been returned, first-tier entities must notify MetroPlusHealth in writing by emailing **delegationoversight@metroplus.org.**

Record Retention

42 CFR 422.504(d) and (e), Medicaid Managed Care Contract: Section 19. Managed Long Term Care Partial Capitation Contract, Article VIII. E.

To comply with regulatory requirements, your organization must maintain records, including all supporting documentation of compliance, for a minimum of ten (10) years from the termination date of the contract or the date of the completion of any audit.

You should be able to produce these records upon MetroPlusHealth' request.

Information Privacy

To comply with all applicable Information Privacy requirements, including those laid out in the applicable Business Associate Agreement, your organization must be HIPAA and NYS Privacy Law compliant.

Your organization must:

- ✓ Have information privacy policies and procedures
- ✓ Provide information privacy training to all your employees (including temporary staff, volunteers, consultants, and governing body members)
- ✓ Document that downstream entities (subcontractors) are also providing required training to their employees (including temporary staff, volunteers, consultants, and governing body members)
- ✓ Ensure training and education is completed within 90 days of initial hire or the effective date of contracting, and at least annually thereafter

OFFSHORE ENTITIES

MetroPlusHealth cannot enter into any agreement with a first-tier entity that has offshore operations that will be involved in the receipt, processing, transferring, storing and/or accessing of its Protected Health Information (PHI).

If you perform services offshore as described above, you must notify MetroPlusHealth immediately.

OVERSIGHT OF FIRST- TIER AND DOWNSTREAM ENTITIES

At all times, MetroPlusHealth maintains ultimate responsibility for fulfilling the terms and conditions of its contracts with CMS and DOH. There regulatory agencies have the authority to hold us accountable for any failure to meet these requirements even if the failure is due to a delegated vendor's non-compliance. CMS requires that we develop a strategy to monitor and audit our first-tier entities to ensure that they are in compliance with all applicable laws and regulations, **and** to ensure that the first-tier entities are monitoring the compliance of the entities with which they contract (MetroPlusHealth downstream entities).

You should expect the following:

1. Ongoing monitoring and auditing throughout the year using metrics provided by you monthly, quarterly, or annually to ensure compliance with service level agreements and applicable Federal and State regulatory and plan requirements
2. A monthly exclusion/sanctions check attestation
3. An annual attestation, whereby you will attest to the previous year's adherence with federal and/or state compliance program requirements
4. Operational Audits at a frequency determined by MetroPlusHealth
5. Annual listing and attestation of subcontractors
6. For identified deficiencies, we will request root cause analysis and implementation of corrective actions

In addition to these requirements, TPMOs will have to annually attest to their adherence with the CMS Medicare Marketing and Communications guidelines, 42 CFR § 422.2274 and 42 CFR § 422.2267(e)(41).

An authorized representative from your organization is required to complete these monthly and yearly attestations. Authorized representatives may include, but are not limited to, a Compliance Officer, Chief Medical Officer, Practice Manager/Administrator, Provider, and Executive Officer, or similar related positions.

Downstream Entities

MetroPlusHealth must be notified of any new subcontractors before entering into contract with third party vendors or subcontractors to perform MetroPlusHealth's delegation. You are required to conduct oversight of your subcontractors (downstream entities). As part of the annual audit, we will request evidence of this oversight to include but not limited to the following:

1. Contractual agreements contain all CMS required provisions
2. Adherence to the Compliance program requirements described in this guide
3. Compliance with any applicable operational requirements
4. Policies and procedures
5. Audit schedule
6. Audit plan/risk assessment
7. Monitoring of entities with results
8. Audit reports

FDR REQUIREMENTS RESOURCE SHEET

MetroPlusHealth wants to ensure that our Vendors comply with the requirements. Therefore, we have created a resource sheet for your reference with the requirements to make it easier for our FDR to comply.

First Tier Entity Requirements Resource Sheet	
Requirement	**Time Frame/Expectation**
Distribution of Code of Conduct/Policies	Within 90 days of hire and at least annual thereafter
Compliance, FWA and Privacy Training for its employees (including temporary staff, volunteers, consultants, governing body members and downstream entities (subcontractors)	Within 90 days of hire or contracting, and at least annual thereafter
Exclusion and Sanction Screenings: Employees (including temporary staff, volunteers, consultants, governing body members and downstream entities (subcontractors) and providers Refer to Guide Section: Exclusion and Sanctions Screening databases to be screened	Employees/Downstream Entities: Before hire/ contracting and monthly thereafter Providers: Initial and recredentialing Maintain evidence of exclusion verification
Record Retention	Retain documentation for a minimum 10 years
Reporting of FWA and Non-Compliance issues	Issues of noncompliance or FWA must be reported immediately
Overpayments	Report, return and explain overpayments to the appropriate government agency within 60 days of identification Notify MetroPlusHealth once the overpayment has been returned
Oversight of Downstream Entities	Monitoring/Auditing of Downstream Entity Compliance Program Notify MetroPlusHealth of new subcontractors prior to entering into contract
Offshore Entities	No offshore contracting permitted Notify MetroPlusHealth immediately if offshore services are performed

Any questions related to these materials, please contact **delegationoversight@metroplus.org**

MetroPlusHealth

metroplus.org

Office of Corporate Compliance 212.908.5100

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