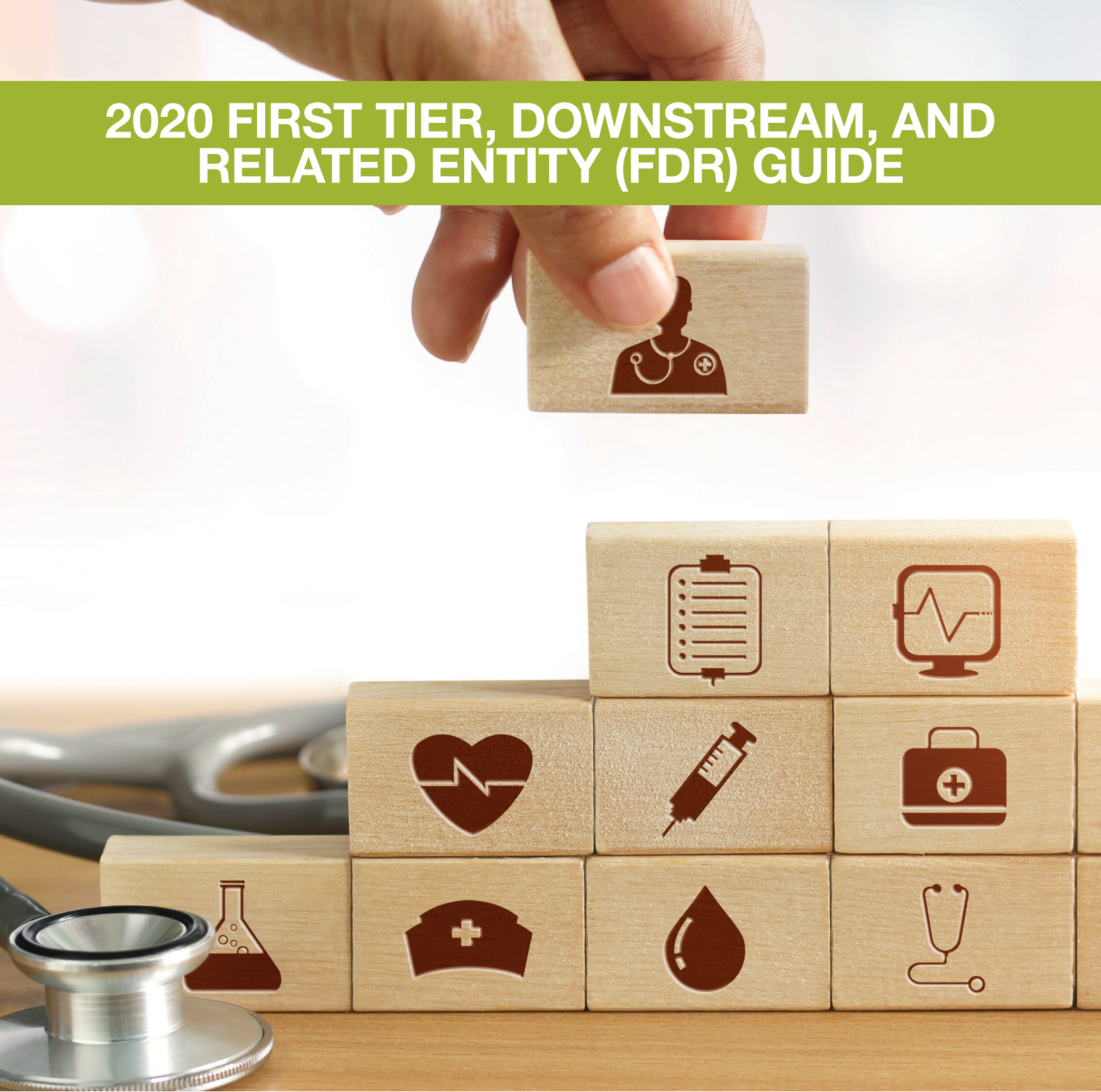


# 2020 FIRST TIER, DOWNSTREAM, AND RELATED ENTITY (FDR) GUIDE



160 Water Street, 4<sup>th</sup> Floor  
New York, NY 10038



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## MESSAGE FROM THE PRESIDENT AND CEO

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MetroPlus Health Plan (MetroPlus) 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 MetroPlus, 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 and Office of Medicaid Inspector General exclusion 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](mailto:DelegationOversight@metroplus.org)



Talya Schwartz, MD  
*President and CEO*  
MetroPlus Health Plan

## DEFINITIONS

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**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.

**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 MetroPlus.

**Downstream Entity** is 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. (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

**OIG** is the Office of the Inspector General within DHHS. The Inspector General is responsible for audits, evaluations, investigations, and law enforcement efforts relating to DHHS programs and operations, including the Medicare program

**GSA** means General Services Administration

**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).

**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?

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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 Medicare Parts C and D contracts. Below are examples of functions that relate to the health plans 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.

If you are involved in any of the above, 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. 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

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Medicare and Medicaid Participation Compliance Program Requirements  
Compliance, Fraud, Waste and Abuse Training and Code of Conduct  
([final rule 2018-07179.pdf](#)) (18 NYCRR 521)

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 we're 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 relevant program requirements **and** must ensure that their subcontractors (MetroPlus' downstream entities), which are used for our products, also comply with applicable laws, and regulations, including the requirements in this guide.

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 prevent, detect, and correct Medicare and Medicaid non-compliance, fraud waste and abuse, and address improper conduct in a timely and well-documented manner. This program should include training and education of 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 initial hire or the effective date of contracting, and at least annually 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. 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.

## **Exclusion and Sanctions Screening**

(Medicare Managed Care Manual Ch. 21 §50.3)

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

Federal law prohibits Medicare, Medicaid 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. Your organization must perform individual and entity checks for all employees, board members, vendors, and contractors **prior to hire** against exclusion lists mentioned below to ensure that no individual is excluded or becomes excluded from Medicare and Medicaid.

- 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

- 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 Assets Controls (OFAC)

If excluded individuals are identified, you must notify MetroPlus of the excluded individual’s name and exclusion date immediately. Also, you must immediately remove the person from work directly or indirectly related to MetroPlus.

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.

Mechanisms for Reporting Suspected Fraud, Waste and Abuse and Non Compliance  
(*Medicare Managed Care Manual Ch. 21 §50.4.2*)



MetroPlus 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.

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

*Call:*

1.888.245.7247 (In reporting via the hotline you are able to remain anonymous)

*Write:*

MetroPlus Health Plan  
Special Investigations Unit  
160 Water Street, 2nd Floor  
New York, NY 10038

*E-Mail:*

Compliance Department at [fraud@metroplus.org](mailto: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.

**Record Retention**

42 CFR 422.504(d) and (e)

To comply with regulatory requirements, your organization must maintain records 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 MetroPlus' 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**

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MetroPlus 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 MetroPlus immediately.

## METROPLUS OVERSIGHT OF FIRST TIER AND DOWNSTREAM ENTITIES

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At all times, MetroPlus maintains ultimate responsibility for fulfilling the terms and conditions of its contracts with CMS and DOH. These 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 (MetroPlus 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 to the rules of compliance and fraud, waste and abuse training, exclusion sanctions check, and other compliance requirements
4. Annual onsite and/or desk audit
5. Annual listing and attestation of subcontractors
6. For identified deficiencies, we will request root cause analysis and implementation of corrective actions

### Downstream Entities

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 requirement
4. Policies and procedures
5. Audit schedule
6. Audit plan/risk assessment
7. Monitoring of entities with results
8. Audit reports

