First Tier, Downstream, & Related Entities (FDR) Medicare Compliance Guide

Capital

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I. What is an FDR?

An “FDR” is a Centers for Medicare & Medicaid (CMS) acronym that means first tier, downstream or related entity.

Current CMS definitions:

First tier entity is any party that enters into a written arrangement, acceptable to CMS, with a Medicare Advantage (MA) organization or Part D plan sponsor.

These arrangements provide administrative or health care services to a Medicare-eligible individual under the MA program or Part D program.

Downstream entity is any party that enters into a written arrangement, acceptable to CMS, with persons or entities. These persons or entities are involved with the MA benefit or Part D benefit. They are below the level of the arrangement and between the following:

- An MA organization.
- A Part D plan sponsor.
- A first-tier entity.

These arrangements continue down to the level of the ultimate provider of both health and administrative services.

Related entity means any party that holds common ownership or control of an MA organization or Part D sponsor and:

- Performs some of the MA organization or Plan D plan sponsor’s management functions under contract or delegation.
- Furnishes services to Medicare enrollees under an oral or written agreement.
- Leases real property or sells materials to the MA organization or Part D plan sponsor (this occurs at a cost of more than $2,500 during a contract period).

For more information, review the United States Code, 42 CFR §§422.500 and 432.501.

CMS FDR definitions and requirements can be found in the Medicare Managed Care Manual Chapters 9 and 21—Compliance Program Guidelines and Prescription Drug Benefit Manual (updated January 11, 2013; pages 3, 5, and 7). Available at: CMS.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf.

Health care providers are FDRs, too.

The compliance requirements in this guide apply to health care providers contracted with our Medicare network. This includes physicians, hospitals, and other provider types.

Here are three reasons why:

1. According to MA regulations and CMS rules, providers who are contracted with us to provide health care services are first tier entities.
2. Chapter 21 §40 of the CMS Medicare Managed Care Manual lists health care services as an example of the types of functions a third party can perform. These functions are in relation to an MA organization's contract with CMS. This gives third parties first tier entity status. This means CMS compliance requirements apply to providers that provide health care services.
3. The flowchart in the same chapter and paragraph shows that entities providing health services and hospital groups are first tier entities. But if we contract with a hospital group and do not have a direct contract with the group's hospitals and providers, the hospitals and providers are downstream entities.

What administrative services do FDRs provide?

Some examples of administrative functions are:

- Claims processing.
- Patient management.
- Credentialing*.

Additional examples of FDRs include:

- Delegates.
- Sales Agents.
- Broker organizations.
- Pharmacies.
- Other individuals, entities, vendors, or suppliers contracted with us for administrative and/or health care services for our Medicare plans.

Medicare compliance program requirements also apply to entities we contract with for administrative services for our MA or Part D contracts. You will find stakeholder relationship flowcharts in chapter 21 §40 of the CMS Medicare Managed Care Manual.

*Under our MA contract with CMS, we are required to credential health care providers that participate in our Medicare network. We may contract with entities to perform these credentialing services on our behalf under a delegation agreement. CMS considers these delegated credentialing entities to be first tier entities. CMS identifies delegated credentialing entities as first tier entities in chapter 11, §100.5 of the 2013 CMS Medicare Managed Care Manual.

II. Partnering to do the right thing.

Our partnership with you—a first tier, downstream or related entity (FDR)—is important to us. We need you to help fulfill our contracts with CMS. And you can rely on us for the teamwork and support you need. Together, we will provide quality administrative and health care services for Capital Blue Cross Medicare members.

Capital Blue Cross offers several types of Medicare plans:

- MA HMO and PPO plans.
- Medicare Prescription Drug Plans (PDPs).

Fulfilling compliance requirements.

As a Capital Blue Cross FDR, you—and providers that support our Medicare Part C and D products—must fulfill specific Medicare compliance requirements. We describe those requirements in this guide.

Compliance resource:	How to use:
Electronic Code of Federal Regulations	Search the United States Code by title. (The United States Code is also referred to as federal regulations.)
Compliance chapters in Medicare manuals	These include: • Chapter 21 of the CMS Medicare Managed Care Manual. • Chapter 9 of the CMS Medicare Prescription Drug Benefit Manual.

III. FDR Medicare compliance requirements.

Capital Blue Cross is responsible for fulfilling the terms and conditions of our contract with CMS and meeting applicable Medicare program requirements. Our FDRs are responsible for complying with these requirements. And they must ensure that their downstream entities also comply with applicable laws and regulations. This includes the requirements in this guide.

Review compliance program requirements.

This guide summarizes Medicare compliance program requirements. Be sure to review it and comply with these requirements each calendar year. Here are some of the actions you must take:

- Distribute a code of conduct or a compliance policy.
- Distribute general compliance and Fraud, Waste, and Abuse (FWA) education and training.
- Complete exclusion list screenings (prior to hire/contracting and monthly).
- Make employees aware of reporting mechanisms.
- Report FWA and compliance concerns to us.
- Report and request to use offshore operations.
- Fulfill specific federal and state compliance obligations.
- Monitor and audit first tier, downstream and related entities.

What can happen if you do not comply?

If you fail to meet CMS Medicare compliance program requirements, it may lead to:

- Development of a corrective action plan.
- Retraining.
- Termination of your contract and relationship with us.

Our response to noncompliance depends on the severity of the issue. As a Capital Blue Cross FDR, if you discover a compliance issue, you must take quick action to fix the issue. And you need to prevent it from happening again.

Confirm completion of requirements.

You must keep evidence of your compliance with these requirements for at least 10 years. This evidence may include employee training records and completed exclusion list screenings.

Medicare Compliance performs various oversight activities each year to test your organization’s compliance with the requirements outlined in this guide. In addition, we may conduct an audit, a monitoring event, or ask you to complete an attestation.

Each year you will be sent an **attestation** and it must be signed by someone in your organization who has responsibility, directly or indirectly, for all:

- Employees.
- Contracted personnel.
- Providers and practitioners.
- Vendors that provide health care and/or administrative services for our Medicare plans.

The signee could be your compliance officer, chief medical officer, practice manager or administrator, an executive officer, or someone else in a similar position.

IV. FDR compliance to-do list.

A. Distribute a code of conduct or a compliance policy.

As a Capital Blue Cross FDR, you must provide our code of conduct and our Medicare compliance policies (or a document of your own that is comparable to both of those documents) to your employees and downstream entities. If you provide your own comparable version, it must explain your commitment to compliance with federal and state laws, ethical behavior, and compliance program operations.

You must provide this material:

- Within 90 days (about three months) of hire or the effective date of contracting.
- When there are updates to the standards of conduct.
- Annually thereafter.
- Show proof that you provided the standards of conduct.

B. Complete compliance and fraud, waste, and abuse (FWA) education and training.

CMS no longer requires FDRs to complete these training courses:

- January 2019 Medicare Parts C and D General Compliance.
- January 2019 Combating Medicare Parts C and D FWA.

Instead, you may use and complete your own version of general compliance and FWA training. It can be specific to your organizational needs.

You can find the requirements for, and more information about, deemed status in:

- CMS Medicare Managed Care Manual, chapter 21 §50.6.61.
- CMS Medicare Prescription Drug Benefit Manual, chapter 9.
- United States Code:
  - Medicare Advantage (MA) plans: 42 CFR §422.503(b)(4)(vi)(C).
  - Medicare Part D, Prescription Drug Coverage: 42 CFR §423.504(b)(4)(vi)(C).

When must education and training be completed?

Required education and training must be completed:

- Within 90 days of initial hire or the effective date of contracting.
- When materials are updated.
- Annually thereafter.

If you use training logs or reports as evidence of completion, they must include:

- Employee names.
- Dates of completion.
- Passing scores (if captured).

Prevent and detect FWA.

To prevent and detect FWA we ask for your cooperation. As a Capital Blue Cross FDR, you play a significant role in protecting the integrity of the Medicare program. To combat FWA, you need to know what it is. And you need to know how to protect your organization from engaging in abusive practices and/or civil or criminal law violations.

What is fraud, waste, and abuse?

Fraud is intentionally misusing information to persuade another person or entity to part with something of value or to surrender a legal right. It could also be an act of planned deception or misrepresentation.

Waste is using, consuming, spending, or expending resources thoughtlessly or carelessly.

Abuse is providing information or documentation for a health care claim in a manner that improperly uses program resources for personal gain or benefit. However, there is not enough evidence to prove criminal intent.

Get to know fraud, waste and abuse laws.

Federal laws govern Medicare FWA. They include:

- Anti-kickback statute (31 U.S.C. §§3729-3733).
- Criminal code (18 U.S.C. Section 1347).
- False Claims Act (31 U.S.C. §§3729-3733).
- Social Security Act (42 U.S.C. chapter 7).
- Stark law (42 USC §1395nn).

These laws state the criminal, civil and administrative remedies the federal government may impose when FWA is committed. Violating these laws may result in:

- Nonpayment of claims.
- Civil money penalties.
- Exclusion from all federal health care programs.
- Criminal and civil liability

The CMS website is a reliable source of additional information. It includes FWA training options.

C. Complete exclusion list screenings.

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 these federal programs. So, before hiring or contracting and monthly thereafter, each FDR must check

exclusion lists. This will help confirm that your employees and downstream entities are not excluded from participating in federally funded health care programs.

Use these websites to perform your exclusion list screening:

- General Service Administration (GSA) System for Award Management (SAM).
- Office of Inspector General (OIG) List of Excluded Individuals and Entities (LEIE).

Your organization must maintain evidence that you have screened against both lists. You must maintain this evidence for a period of 10 years. This includes source documentation such as screenshots, input lists and/or documentation with date stamps. You may keep logs that track the dates for all screened employees and FDR. This will help track exclusion screenings. Also, make sure to keep source documentation.

Perform screenings regularly.

The following individuals and entities must be screened before hiring or contracting and then monthly thereafter:

- Employees.
- Temporary employees.
- Volunteers.
- Consultants.
- Members of your governing body.
- FDRs

To comply with CMS requirements, your organization needs to check both the OIG and the GSA exclusion lists. This will ensure these individuals and entities are not excluded.

Take action with those on exclusion lists.

If any of your employees or downstream entities are on an exclusion list, you must immediately:

- Remove them from any direct or indirect work on our Medicare plans.
- Notify us.

You will find the exclusion list requirements in:

- CMS Medicare Managed Care Manual, chapter 21 §50.6.8.
- CMS Medicare Prescription Drug Benefit Manual, chapter 9, §50.6.8.
- Social Security Act, §1862(e)(1)(B).
- United States Code—42 CFR §§422.503(b)(4)(vi)(F)—422.752(a)(8)—423.504(b)(4)(vi)(F)—423.752(a)(6)—1001.1901.

D. Report FWA and compliance concerns to us.

There are several ways to report suspected or detected noncompliance or potential FWA. You'll find them on our reporting mechanism poster. All reports are confidential. Share the poster with your employees and downstream entities. Or keep it as a reference tool and use your own internal processes for reporting and collecting these issues. Refer to our code of conduct for more information on our reporting guidelines. If you use your own code of conduct or compliance policies, you must include a process for reporting all compliance and FWA issues that impact Capital Blue Cross.

Enforce a zero-tolerance policy for retaliation.

There can be no retaliation against or coercion of anyone reporting suspected misconduct.

How to report FWA and Medicare Compliance concerns to us?

Call us at **888.511.4036**.

Email us at **CBCMedicareCompliance@CapBlueCross.com**.

Write to us at:

Capital Blue Cross
Compliance Department
P.O. Box 776044
Harrisburg, PA 17177-6044

E. If you conduct offshore business.

Offshore entity means an individual or entity physically located outside the United States or one of its territories. An offshore entity will or may receive, process, transfer, handle, store, or access to protected health information (PHI)—in oral, written, or electronic form.

Protected health information (PHI) refers to the types of personal information listed in the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. PHI includes information such as name and address, medical history, and current health status.

Offshore services mean the offshore entity will or may receive, process, transfer, handle, store, or access the PHI—in oral, written, or electronic form—of Capital Blue Cross Medicare Advantage members.

If your activities involve PHI, we will submit an attestation of that fact to the Centers for Medicare & Medicaid (CMS).

Examples of offshore entities.

- An offshore radiologist who receives radiological images, reads them, and transmits diagnoses back to the U.S.
- A billing company that performs services offshore.

Offshore requirements.

- If you already use an offshore entity, tell us right away.

1. **Get written approval before you perform services.**

   Offshore written approval must be granted to you by an authorized Capital Blue Cross representative before you can:

   - Perform offshore services for our Medicare plans.
   - Use an individual or entity to perform offshore services for our Medicare plans.

2. **Notify us again if there are material changes.**

   If there are material changes in any offshore services information that you submitted in the past, tell us right away. (Material changes means that any Offshore Services approval that we granted is void.) You must submit a new Offshore Services Attestation form with the latest information.

F. Fulfill federal and state compliance obligations.

You may be subject to other federal and state laws, rules, and regulations. You'll still need to fulfill these, but they aren't covered in this guide. We expect your organization to comply with all applicable federal and state laws, rules, and regulations. If you have questions about the compliance obligations for the services your organization performs, ask your Capital Blue Cross relationship manager.

G. Monitor and audit first tier and downstream entities.

CMS requires us to develop and implement a strategy for monitoring and auditing our first-tier entities. This helps ensure they comply with all applicable laws and regulations. We routinely monitor and periodically audit our FDRs. This helps us ensure compliant administration of our CMS contracts. And it ensures compliance with applicable laws and regulations.

Each FDR must take part in these monitoring and auditing activities. If you complete your own audits, we may ask for the results affecting our Medicare business. If you fail to comply with the requirements in this guide, we will expect you to submit a corrective action plan. We can help you address the identified issues.

Incident Reporting Form (IRF).

Upon discovery of an issue that requires reporting to Medicare Compliance, your Capital business area will complete and submit an IRF. The discovery can be an issue discovered through

- Plan monitoring or;
- You may report the issue directly to us.

We will actively engage with you, as needed, to ensure that the issue is addressed fully. Additional corrective action monitoring may also be put in place.

Not every subcontractor is a downstream entity.

Only subcontractors that provide administrative or health care services for our Medicare Advantage and Prescription Drug plan products may be downstream entities. Review this downstream entity requirements description to help you determine who is a downstream entity. Email us at **CBCMedicareCompliance@capbluecross.com** if you have any questions.

Take action to ensure compliance. You must conduct enough oversight (auditing and monitoring) to test and ensure your employees and downstream entities are compliant. You must:

- Retain evidence of this oversight.
- Ensure that root cause analysis is conducted for any deficiencies.
- Implement corrective actions, including disciplinary actions, including contract termination, to prevent recurrence of noncompliance.

V. FDR tool kit.

You can use this FDR Tool Kit tool to assess how you fulfill Medicare compliance program requirements. Your organization can modify the tool to assess compliance of your downstream entities.

Code of conduct and compliance policies	
Don't have your own code?	Feel free to distribute our code of conduct to your employees.
You can use our Medicare policies.	Feel free to distribute our Medicare compliance policies to your employees, too.
Exclusion list screenings	
The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) exclusions database.	Complete OIG exclusion list screenings before hiring or contracting, and each month thereafter, for your employees and downstream entities. This sample log provides a way to track your screenings. Don't forget, you need to also maintain source documentation of your screenings, such as screenshots and input lists.
General Service Administration (GSA) System for Award Management (SAM).	Complete the SAM exclusion list screenings before hiring or contracting, and each month thereafter, for your employees and downstream entities. This sample log provides a way to track your screenings.
Reporting mechanisms	
How to report noncompliance or potential fraud, waste and abuse (FWA).	Remember, you must report suspected or detected noncompliance or potential FWA to us. Our reporting mechanism poster shows you how. Feel free to share it throughout your organization so your employees know how to report concerns.
Monitoring and oversight	
Downstream entity oversight.	You must conduct oversight of your downstream entities. An FDR attestation may help your downstream entities self-monitor and report the status of their compliance to you.
Which subcontractors are downstream entities?	Not every subcontractor is a downstream entity. Read downstream entity requirements for examples of those that are.

Offshore Services Attestation form

Use this Offshore Services Attestation form to request permission for you or your subcontractor to use an offshore individual or entity.

Request to perform any of these services for Medicare member PHI:

- Processing.
- Transferring.
- Handling.
- Storing.
- Accessing.

Email your completed form to **CBCMedicareCompliance@capbluecross.com** and put “New offshore submission” in the subject line.

Report fraud, waste, abuse, ethics, and compliance concerns in **THREE EASY STEPS**

1 Call us at **888.511.4036**.

2 Email us at **CBCMedicareCompliance@CapBlueCross.com**.

3 Write to us at:

Capital Blue Cross
Compliance Department
PO Box 776044
Harrisburg, PA 17177-6044

All reports are treated confidentially. You may also choose to remain anonymous. Our policy prohibits retaliation against any individual who in good faith reports suspected violations.

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Offshore services attestation

To be completed that this contracted entity:
(Note: one attestation is required for each offshore entity)

(A) contracts directly with Capital Blue Cross and has a contract with a vendor that receives, processes, transfers, handles, stores, or accesses Medicare member PHI offshore

OR

(B) contracts directly with Capital Blue Cross, and has a contract with another further subcontracted vendor, and that vendor will be supporting or performing work for our Medicare plans. Or they may support the work one of our first-tiers does for our Medicare plans, and receives, processes, transfers, handles, stores, or accesses Medicare member Protected Health Information ("PHI") offshore.

Submission of this "Offshore Services Attestation" is due back to Capital Blue Cross at least 30 days prior to the effective date of the offshore activity or service is scheduled to begin.

Name of contracted entity:

_____

Offshore entity name:

_____

Offshore entity country or countries, if multiple locations:

_____

_____

Offshore entity address or addresses, if multiple locations (the offshore entity address should include the full address for each offshore location, including the country, which will receive, process, transfer, handle, store, or access PHI):

_____

_____

Describe offshore functions the offshore entity will perform ("offshore services"):

_____

_____

State the proposed or actual effective date for the aforementioned offshore services: (The proposed or actual effective date is either the effective date of the Medicare contract with Capital Blue Cross or the effective date of the contract with the entity, whichever is later. The proposed or actual effective date for the services must include the month, date, and year. Please use this format: MM/DD/YYYY).

_____

Description of the PHI that will be provided to the offshore entity (please check the boxes below to identify the types of PHI the offshore entity may access):

☐ Name	☐ Age	☐ Date of birth	☐ Address	☐ Phone number
☐ Full SSN	☐ Partial SSN (last four)	☐ Capital Blue Cross member ID	☐ Prescription history	☐ Claims history
☐ Diagnosis	☐ Medical history	☐ Banking/financial information		

☐ Other (please provide a detailed description):

_____

Explain why providing PHI is necessary to accomplish the offshore services:

_____

_____

Describe all alternatives considered to avoid providing PHI. Why was each alternative rejected? (When describing any alternatives considered to avoid using PHI, be sure to include the reason why the alternative was rejected):

_____

_____

_____

With respect to the offshore services provided by the above-named offshore entity, first-tier certifies and attests that:

YES ☐ NO ☐ The agreement it has with the offshore entity requires the offshore entity to have policies and procedures in place to ensure that Capital Blue Cross Medicare Plans' PHI remains secure.

YES ☐ NO ☐ (ii) The agreement it has with the offshore entity prohibits the offshore entity's access to data not associated with the agreement.

YES ☐ NO ☐ (iii) The agreement with the offshore entity allows the first-tier to immediately terminate the offshore services upon discovery of a significant security breach.

YES ☐ NO ☐ (iv) The agreement it has with the offshore entity includes all required Medicare Part C and Part D language (e.g., record retention requirements, compliance with all Medicare Part C and D requirements, etc.).

YES ☐ NO ☐ (v) The contracted entity conducts an annual audit or review of its relationship with the offshore entity.

YES ☐ NO ☐ (vii) The results from the annual audit or review are used to evaluate the continuation of the relationship with the offshore entity.

YES ☐ NO ☐ (vii) The agreement it has with the offshore entity requires the offshore entity to share such audit results with the Centers for Medicare and Medicaid Services (“CMS”) directly or with a plan sponsor (Capital Blue Cross.) upon request.

YES ☐ NO ☐ (viii) Additional information about its agreement with the offshore entity will be provided to CMS directly or its authorized agents or a plan sponsor (here, Capital Blue Cross) upon request.

YES ☐ NO ☐ (ix) The first-tier understands the clean-room requirements provided with this document.

Please provide a brief explanation for any “no” responses for statements above.

_____

_____

I certify, as an authorized representative of my organization, that the statements made above are true and correct to the best of my knowledge. In addition, my organization agrees to maintain documentation supporting the statements above. My organization will produce evidence of the above to Capital Blue Cross. or CMS upon request. My organization understands that the inability to produce this evidence will result in a request from Capital Blue Cross for a Corrective Action Plan (“CAP”) or other contractual remedies, such as contract termination.

Print name of authorized representative from entity:

_____

Print title of authorized representative from entity:

_____

Signature of authorized representative from entity: Date of signature:

_____

Representative (address, city, state, Zip Code):

_____

Representative email address:

_____

Entity name (printed):

_____

Tax ID number or employer ID number: NPI number:

Please return to:

Capital Blue Cross
Attention: Medicare Compliance Officer
2500 Elmerton Avenue
Harrisburg, PA 17177

Email: CBCMedicareCompliance@CapBlueCross.com