

CHRISTUS Health Plan



Medicare First Tier,
Downstream and
Related Entities
(FDR) Guide



CHRISTUS[®]
Health Plan

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

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I. Introduction – CHRISTUS Health Plan’s Medicare compliance program

CHRISTUS Health Plan (CHP) is committed to maintaining a working environment that promotes our Mission, working in accordance with our Core Values and compliance with all applicable federal and state laws. Such an environment can exist only if CHRISTUS Associates, directors, and Health Care Partners (e.g. physicians, other health professionals, volunteers, vendors, contractors, subcontractors, suppliers and agents) strive to fulfill the Mission and work in accordance with our Core Values in performing their daily tasks.

Our Medicare compliance program helps us serve our members ethically

We’re committed to practicing business in an ethical manner. Our Medicare compliance program helps us to:

- Reduce or eliminate fraud, waste and abuse (FWA)
- Make sure we comply with applicable laws, rules and regulations
- Reinforce our commitment to compliance

We use external entities to bring our members cost-effective health care solutions

CHP offers Medicare Advantage (MA) plans. We contract with external entities and individuals as a cost-effective and efficient way of providing administrative and health care services on our behalf. Some of the services provided by external entities are services that we are required to perform under our contract with the Centers for Medicare & Medicaid Services (CMS). CMS refers to these entities as First Tier, Downstream and Related Entities (FDRs).

You will find specific requirements in this document

CMS also requires that CHP’s FDRs fulfill specific Medicare compliance program requirements in this document. The Code of Federal Regulations (CFR) outlines these requirements, and they are defined by CMS in the January 11, 2013, Compliance Program Guidelines in Chapter 21 of the [Medicare Managed Care Manual](#) (manual) and Chapter 9 of the [Prescription Drug Benefit Manual](#). The requirements are identical in these two resources.

Importance of following requirements

You received this guide because we’ve identified you as a First Tier Entity. This means that you must comply with these requirements.

II. What is an FDR?

CHP uses the current CMS definitions to define First Tier, Downstream and Related Entities:

First Tier Entity is any party that enters into a written arrangement, acceptable to CMS, with an MA organization 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 CFR § 422.500 and 423.501.)

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 MA organization 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 CFR § 422.500 and 423.501.)

Related Entity means any entity that is related to an MA organization or Part D sponsor by common ownership or control and:

- Performs some of the MA organization or Part 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 at a cost of more than \$2,500 during a contract period (See 42 CFR § 422.500 and 423.501.)

FDRs providing health care services

The Medicare compliance program requirements described in this guide apply to health care providers contracted with CHP to participate in our Medicare network. This includes physicians, hospitals, and other provider types. Here are the reasons why:

- MA regulations and CMS rules state that providers contracted with CHP to provide health care services to our Medicare members are “First Tier Entities.”
- Chapter 21 of the manual lists “health care services” as an example of the types of functions that a third party can perform that relate to an MA organization’s contract with CMS. This would give third parties “First Tier Entity status. (See last bullet point in the manual, Chapter 21 § 40.) So these requirements apply to providers that actually deliver health care services to our Medicare members.
- CMS provides a chart in the manual, Chapter 21 § 40, showing that entities providing health services and hospital groups are First Tier Entities. So if CHP contracts with a hospital group and don’t have a direct contract with the group’s hospitals and other providers, the hospitals and providers are Downstream Entities. This means that the hospital group is a First Tier Entity and must comply. It also must make sure its Downstream Entities comply with the CMS compliance program requirements in this guide.

FDRs providing administrative services

The Medicare compliance program requirements also apply to entities with which we contract to perform administrative service functions relating to our MA or Part D contracts with CMS. Some examples of administrative service functions include:

- Claims processing
- Patient management
- Credentialing*

Other examples of FDRs include delegates, agents, broker organizations, pharmacies and other individuals, entities, vendors or suppliers contracted with CHP to provide administrative and/or health care services for our Medicare plans. You can find more information in the manual, Chapter 21 § 40, including the Stakeholder Relationship Charts.

**Under our MA contract with CMS, we're 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 entities as First Tier Entities in the manual, Chapter 11§ 100.5.*

III. FDR Medicare compliance program and attestation requirements?

It's important that CHP FDR's are in compliance with applicable laws, rules and regulations. Although we contract with FDRs to provide administrative and/or health care services for our Medicare plans, in the end, we're 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 relevant Medicare program requirements. FDRs must also ensure that their Downstream Entities, which they use for our CHP MA plans, also comply with applicable laws and regulations, including the requirements in this guide.

Compliance Program Requirements

Your organization and all of your Downstream Entities must comply with Medicare compliance program requirements. This guide summarizes the Medicare compliance program requirements. Please review it to make sure you have internal processes to support your compliance with these requirements each calendar year. These Medicare compliance program requirements include, but are not limited to:

- Effective January 1, 2016, completion of the CMS *Combating Medicare Parts C and D Fraud, Waste, and Abuse Training* and the CMS *Medicare Parts C and D General Compliance Training* modules
- Code of conduct/compliance program policy distribution
- Exclusion list screenings
- Reporting FWA and compliance concerns to CHP
- Offshore operations and CMS reporting
- Specific federal and state compliance obligations

- Monitoring and auditing of First Tier, Downstream and Related Entities

For tools that may help you meet these requirements, please see “Toolbox of resources for FDRs” at the end of this guide.

What may happen if you don’t comply with CMS Medicare Requirements?

If our FDRs fail to meet these CMS Medicare compliance program requirements, it may lead to:

- Development of a corrective action plan (CAP)
- Retraining
- Termination of your contract and relationship with CHP

Our actions in response to noncompliance will depend on the severity of the compliance issue. If an FDR identifies areas of noncompliance (for example, refusal of an employee to complete the required FWA training), they must take prompt action to fix the issue and prevent it from happening again.

Attestation requirements

You must maintain evidence of your compliance with these Medicare compliance program requirements (for example, employee training records and CMS certificates of FWA training completion) for no less than 10 years. Also, each year, an authorized representative from your organization must attest to your compliance with the Medicare compliance program requirements described in this guide. The authorized representative is an individual who has responsibility directly or indirectly for all:

- Employees
- Contracted personnel
- Providers/practitioners
- Vendors who provide health care and/or administrative services for CHP MA plans

This could be your compliance officer, chief medical officer, practice manager/administrator, an executive officer or similar positions.

You may be asked to provide evidence of compliance

In addition to completing an attestation, CHP and/or CMS may request that you provide evidence of your compliance with these Medicare compliance program requirements. This is for monitoring/auditing purposes.

If you have questions or concerns about these Medicare compliance program requirements, just contact CHPVendorRelations@christushealth.org.

Please continue reading for a description of each Medicare compliance program requirement.

A. Fraud, waste and abuse (FWA) training and general compliance training

FWA and general compliance training

You must ensure that your applicable employees and Downstream Entities complete fraud, waste and abuse and general compliance training. Effective January 1, 2016, you/your organization must ensure their completion of the CMS [Combating Medicare Parts C and D Fraud, Waste, and Abuse Training](#) module, as well as the CMS <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/MedCandDGenCompdownload.pdf> module. CMS may update these required training modules annually.

Your applicable employees and Downstream Entities assigned to provide administrative and/or health care services for our Medicare plans can access these trainings in one of three ways:

- Complete the modules on the [CMS Medicare Learning network \(MLN\)](#) website. The general compliance course is called *Medicare Parts C and D General Compliance Training*, and the FWA training is called *Combating Medicare Parts C and D Fraud, Waste, and Abuse Training*. Once completed, download and retain the certificate of completion. The certificates must be made available to CHP and/or CMS upon request.
- You/Your organization can also download or print content of the CMS training modules from the MLN website to incorporate it into your training materials/system. The content of the CMS training modules **cannot** be changed to ensure the integrity and completeness of the training. You/Your organization must retain records of completion which must be made available to CHP and/or CMS if requested.
- You/Your organization can incorporate the content of the CMS training modules from the MLN website into written documents for providers (for example, provider guides or participation manuals).

Training requirements

Regardless of the method used, the training must be completed:

- Within 90 days of initial hire or the effective date of contracting
- At least annually during each calendar year (January 1 – December 31) thereafter

We request that you confirm your compliance with these requirements as part of our annual attestation process. However, you must also maintain evidence of training completion. Evidence of completion may be in the form of certificates, attestations, training logs or other means determined by you to best represent fulfillment of your obligations. If you use training logs or reports as evidence of completion, they must include: (i) Employee Names; (ii) Dates of Employment; (iii) Dates of completion; and (iv) Passing scores (if captured).

Who should complete training?

Not every employee needs to take 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 CHP (for example, senior vice president, departmental managers, chief medical or pharmacy officer)
- Individuals directly involved with establishing and administering CHP’s formulary and/or medical benefits coverage policies and procedures
- Individuals involved with decision-making authority on behalf of CHP (for example, clinical decisions, coverage determinations, appeals and grievances, enrollment/disenrollment functions, processing of pharmacy or medical claims)
- Reviewers of beneficiary claims and services submitted for payment
- Individuals with job functions that place the FDR in a position to commit significant noncompliance with CMS program requirements or health care FWA

Please review the attached [grid](#) if you are not sure which employees at your organization should take the training. If you still have questions, you can email CHPVendorRelations@christushealth.org for help.

The only exception to this training requirement is if you/your organization is “deemed” to have met the FWA certification requirements through enrollment into Medicare Part A or B of the Medicare program or through accreditation as a supplier of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). Those parties deemed to have met the FWA training through enrollment into the CMS Medicare program must still complete general compliance training.

For training requirements and information about deemed status see: 42 CFR § 422.503 (b)(4)(vi)(C) for MA, 42 CFR § 423.504 (b)(4)(vi)(C) for Part D, and Manual, Chapter 21 § 50.3

B. Code of conduct/compliance program policy distribution

You must give your employees standards of conduct

Your organization must also provide either [CHRISTUS Health’s Code of Ethics](#) and Medicare compliance policies (available upon request by emailing CHPCompliance@christushealth.org) or your own comparable code of conduct/compliance policies (collectively, “standards of conduct”) to all applicable employees and Downstream Entities who provide administrative and/or health care services for our Medicare plans. The written compliance policies and standards of conduct must contain all of the elements set forth in Section 50.1 and its subsections of Manual, Chapter 21, and articulate the entity’s commitment to comply with federal and state laws, ethical behavior and compliance program operations. You must distribute standards of conduct/policies:

- Within 90 days of hire or the effective date of contracting
- When there are updates to the standards of conduct
- Annually thereafter

Evidence of your distribution of the standards of conduct must be retained. You can find the standards of conduct requirements in:

- 42 CFR § 422.503 (b)(4)(vi)(A) for MA

- 42 CFR § 423.504 (b)(4)(vi)(A) for Part D
- Manual, Chapter 21 § 50.1

C. 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 participation in these federal programs. Therefore, before hiring or contracting, and monthly after that, each FDR must check exclusion lists from the Office of Inspector General (OIG) and the U.S. General Services Administration (GSA). This is to confirm that employees and Downstream Entities performing administrative and/or health care services for CHP's Medicare Plans aren't excluded from participating in federally funded health care programs. You can use these two websites to perform the required exclusion list screening:

- **OIG List of Excluded Individuals and Entities (LEIE)**
- **GSA's System for Award Management (SAM)**

Also, FDRs must maintain evidence they checked these exclusion lists. You can use logs or other records to document that you've screened each employee and Downstream Entity in accordance with current laws, regulations and CMS requirements. Be sure to retain evidence of the screening that was conducted including date of occurrence, the results of the screening and any actions taken if sanctioned individuals or entities were identified.

You must perform exclusion list screenings

You're not alone. We're also required to check these exclusion lists before hiring or contracting with any new employee, temporary employee, volunteer, consultant, governing body member or FDR, and monthly after that. We cannot check these exclusion lists for your employees and Downstream Entities. So to make sure we comply with this CMS requirement, you must confirm that your permanent and temporary employees and Downstream Entities that provide administrative and/or health care services for our Medicare plans are not on either of these exclusion lists.

You must take action if an employee or Downstream Entity is on the exclusion list

If any of your employees or Downstream Entities are on one of these exclusion lists, you must immediately remove them from work directly or indirectly related to CHP's Medicare plans and notify us right away.

These exclusion list requirements are noted in § 1862(e)(1)(B) of the Social Security Act, 42 CFR §§ 422.503(b)(4)(vi)(F), 422.752(a)(8), 423.504(b)(4)(vi)(F), 423.752(a)(6), 1001.1901, and further described in the manual, Chapter 21 § 50.6.8.

D. Reporting FWA and compliance concerns to CHP

There are a number of ways to report suspected or detected noncompliance or potential FWA. Don't worry – your reports are confidential. You can find this information in [CHP's reporting mechanism flyer](#). You can share

the flyer with your employees or Downstream Entities. You can also keep it as a reference tool and use your own internal processes for reporting and collecting these issues. If you choose to use your own processes, make sure you report it to CHP. You can also refer back to our Code of Ethics for information on our reporting guidelines.

You must adopt and enforce a zero-tolerance policy for retaliation or intimidation against anyone who reports suspected misconduct.

CHP's Medicare Compliance Officer, Mike Sullivan, is based at our corporate offices in Irving, TX. Questions or concerns for Mike and/or his Medicare compliance subject matter experts can be sent to CHPCompliance@christushealth.org.

E. Offshore operations and CMS reporting

To help make sure we comply with applicable federal and state laws, rules and regulations, you are required to request permission to perform offshore services or to use an individual or entity (offshore entity) to perform services for CHP's Medicare plans when the individual or entity is physically located outside the United States or one of its territories (that is, American Samoa, Guam, Northern Marianas, Puerto Rico and Virgin Islands). The only approval is made by an authorized CHP representative in advance and in writing for the use of such offshore individual or entity.

Notify us immediately if you plan to use an offshore entity

If you perform services offshore or use an offshore entity to perform services involving the receipt, processing, transferring, handling, storing or accessing of Medicare member protected health information (PHI) and we must approve the arrangement, CHP is required to submit an attestation to CMS. Therefore, you must immediately notify your CHP relationship manager if you engage in offshore services yourself or through an offshore entity.

One example provided by CMS of offshore services that trigger this attestation requirement is "offshore subcontractors that receive radiological images for reading because beneficiary personal health information (PHI) is included with the radiological image and the diagnosis is transmitted back to the U.S."

F. Specific federal and state compliance obligations

Based on the services that you/your organization perform for CHP's Medicare plans, you may be subject to other federal and state laws, rules and regulations that aren't described in this guide. If you have questions about the Medicare requirements for the services that you/your organization perform, consult with your CHP relationship manager. CHP expects you/your organization to be compliant with all applicable federal and state laws, rules and regulations.

G. Monitoring and auditing of First Tier and Downstream Entities

CMS requires organizations such as CHP to develop a strategy to monitor and audit our First Tier Entities. This helps ensure that our First Tier Entities comply with all applicable laws and regulations and that our First Tier Entities must monitor the compliance of their Downstream Entities. Therefore, if you choose to subcontract with other individuals/parties to provide administrative and/or health care services for CHP's Medicare plans, you must make sure that these Downstream Entities abide by all laws and regulations that apply to you as a First Tier Entity. This includes ensuring:

- Contractual agreements contain all CMS-required provisions
- They comply with the Medicare compliance program requirements described in this guide
- They comply with any applicable Medicare operational requirements

Not every subcontractor is considered a Downstream Entity. Only those entities who provide administrative or health care services for CHP's Medicare Advantage and Prescription Drug Plan products may be Downstream Entities. Review this [grid](#) to help you determine who is a Downstream Entity for your organization. If you have additional questions, feel free to contact us for assistance at CHPVendorRelations@christushealth.org.

Additionally, you/your organization must conduct sufficient oversight (that is, auditing and monitoring) to test and ensure that your employees and Downstream Entities are compliant. You must retain evidence of oversight completion, ensure root cause analysis is conducted for any deficiencies, and implement corrective actions or take disciplinary actions such as contract termination, as necessary, to prevent recurrence of noncompliance.

Expect routine monitoring and audits

We routinely monitor and periodically audit our FDRs. This helps us ensure compliant administration of our contracts with CMS to offer Medicare plans, as well as applicable laws and regulations. Each FDR must cooperate and participate in these monitoring and auditing activities. If an FDR performs its own audits, we may ask for the audit results affecting CHP's Medicare business. Also, FDRs must routinely monitor and/or periodically audit their Downstream Entities if they are used for CHP's Medicare plans.

If we determine that an FDR doesn't comply with any of the requirements in this guide, we'll require the FDR to develop and submit a Corrective Action Plan (CAP). We can help the FDR address the identified compliance issues.

These monitoring and auditing requirements are noted in:

- 42 CFR § 422.503(b)(4)(vi)(F) for MA
- 42 CFR § 423.504(b)(4)(vi)(F) for Part D
- Manual, Chapter 21 § 50.6.6

Questions or Concerns

For compliance questions or concerns, you can email us at CHPCompliance@christushealth.org.

For general FDR/Vendor questions or concerns, you can email us at CHPVendorRelations@christushealth.org.

Resources for FDRs

General compliance and FWA training	
CMSgeneralcompliancetraining	Organizations can use the CMS general compliance training module on the CMS Medicare Learning Network (MLN) . It can be completed on the MLN, after registration. It is titled <i>Medicare Parts C and D General Compliance Training</i> . Organizations can download it and incorporate the module, unmodified, into their existing training materials/systems.
CMS FWA training	Organizations can use the CMS FWA training module on the MLN . It can be completed on the MLN, after registration. It is titled <i>Combating Medicare Parts C and D Fraud, Waste, and Abuse Training</i> . Organizations can download it and incorporate the module, unmodified, into their existing training materials/systems.
Proof of training completion	CMS requires FDRs to maintain evidence of training completion. FDRs must retain this evidence for 10 years. The CMS training completion certification is evidence of completion. Organizations may use a sample log to document employees' completion of training. Organization's Downstream Entities can also use this log to document their employees' training completion.
Code of conduct and compliance policies	
Which code should be used?	Organizations are encouraged to distribute CHRISTUS's Code of Ethics to employees.
Which Medicare compliance policies are applicable?	CHRISTUS's Code of Ethics in addition to specific Medicare policies, available upon request, detail the CHRISTUS Medicare compliance program.
What information should be provided to employees?	Organizations may use this announcement template to share CHRISTUS's Code of Ethics and compliance policies with employees and Downstream Entities.
Exclusion list screenings	
How is the OIG site accessed?	Organizations must complete OIG exclusion list screenings before hiring/contracting and monthly after that for your employees and Downstream Entities. Use this OIG/GSA screening log to aid in your process.
How is the GSA's SAM site accessed?	Organizations must complete the GSA's SAM exclusion list screenings before hiring/contracting and monthly after that for your employees and Downstream Entities. Use this OIG/GSA screening log to aid in your process.
Reporting mechanisms	
How is noncompliance or potential FWA reported to CHRISTUS?	Organizations must report suspected or detected noncompliance or potential FWA that impact CHRISTUS directly to CHRISTUS. The following notification information should be shared throughout the organization so that employees know how to report concerns.
Monitoring and oversight	
Which subcontractors are Downstream Entities?	Not every subcontractor is a Downstream Entity. This grid has examples of Downstream Entities.
What type of oversight of Downstream Entities should be done?	Organizations must conduct oversight of your Downstream Entities. An FDR attestation may help your Downstream Entities self-assess and report the status of their compliance to you.
How will the organization know if it is in compliance with Medicare requirements?	Organizations can use this example tool to assess their compliance with the Medicare compliance program requirements. The organization can also modify the tool to assess compliance of Downstream Entities.
What is required regarding Offshore operations?	Organizations must request permission to use an offshore individual or entity to perform services that involve the processing, transferring, handling, storing or accessing of Medicare member PHI. Use this form to request permission and return the completed form to CHPVendorRelations@christushealth.org .